

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

KENNETH A. BARTON and MICHAEL J. MILLER,  
(U.S. Application 07/827,906)

(Barton),

or

DAVID A. FISCHHOFF and FREDERICK J. PERLAK,  
(U.S. Application 08/434,105)

Junior Party (Fischhoff),

v.

MICHAEL J. ADANG, THOMAS A. ROCHELEAU,  
DONALD J. MERLO and ELIZABETH E. MURRAY,  
(U.S. Patent 5,380,831)

Senior Party (Adang)

---

Interference 103,781

---

MAILED  
SEP - 4 2002:  
PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

DECISION AND ORDER ON PRELIMINARY  
AND MISCELLANEOUS MOTIONS AND REQUESTS

---

TEDDY S. GRON, Administrative Patent Judge.

1. Background

September 26, 1983 - Michael J. Adang and John D. Kemp filed U.S. Application 06/535,354, entitled "Insect Resistant Plants" (assignment to Agrigenetics Research Associates Ltd. recorded September 20, 1983; assignment to Lubrizol Genetics Inc. recorded May 29 1986), now abandoned.

April 4, 1986 - Michael J. Adang and John D. Kemp filed U.S. Application 06/848,733, entitled "Insect Resistant Plants" (assignment to Lubrizol Genetics Inc. recorded June 25, 1986), now abandoned, which is claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

September 9, 1988 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray filed U.S. Application 07/242,482, entitled "Synthetic Insecticidal Crystal Protein Gene" (assignment to Lubrizol Genetics Inc. recorded October 24, 1988), now abandoned, which is claimed to be a continuation-in-part of U.S. Application 06/848,733, filed April 4, 1986, which is claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

Interference 103,781

February 24, 1989 - David A. Fischhoff and Frederick J. Perlak filed U.S. Application 07/315,355, entitled "Synthetic Plant Genes And Method For Preparation" (assignment to Monsanto Company recorded February 24, 1989), now abandoned.

August 7, 1989 - Kenneth A. Barton and Michael J. Miller filed U.S. Application 07/390,561, entitled "Expression of Genes In Plants" (assignment to Agracetus recorded August 7, 1989; assignment to Monsanto Company recorded October 15, 1996), now abandoned.

February 12, 1990 - David A. Fischhoff and Frederick J. Perlak filed U.S. Application 07/476,661, entitled "Synthetic Plant Genes And Method For Preparation" (assignment to Monsanto Company recorded February 12, 1990), now abandoned, which is claimed to be a continuation-in-part of U.S. Application 07/315,355, filed February 24, 1989.

January 28, 1992 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray filed U.S. Application 07/827,844, entitled "Synthetic Insecticidal Crystal Protein Gene" (assignment to Mycogen Plant Science, Inc., recorded April 1, 1993), now abandoned, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988, which is claimed to be a continuation-in-part of U.S. Application 06/848,733, filed April 4, 1986, which is

Interference 103,781

claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

January 30, 1992 - Kenneth A. Barton and Michael J. Miller filed involved U.S. Application 07/827,906, entitled "Improved Expression of Genes In Plants" (assignment to Monsanto Company recorded October 15, 1996; assignment to Monsanto Technology LLC recorded June 13, 2001), which is claimed to be a continuation of U.S. Application 07/390,561, filed August 7, 1989.

October 9, 1992 - David A. Fischhoff and Frederick J. Perlak filed U.S. Application 07/959,506, entitled "Synthetic Plant Genes" (assignment to Monsanto Technology LLC recorded June 13, 2001), which is claimed to be a continuation of U.S. Application 07/476,661, filed February 12, 1990, which is claimed to be a continuation-in-part of U.S. Application 07/315,355, filed February 24, 1989.

May 3, 1993 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray filed U.S. Application 08/057,191, entitled "Synthetic Insecticidal Crystal Protein Gene" (assignment to Mycogen Plant Science, Inc., recorded April 1, 1993), which is claimed to be a continuation of U.S. Application 07/827,844, filed January 28, 1992, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988, which is claimed to be a continuation-

Interference 103,781

in-part of U.S. Application 06/848,733, filed April 4, 1986, which is claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

January 6, 1995 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray filed U.S. Application 08/369,839, entitled "Synthetic Insecticidal Crystal Protein Gene," which is claimed to be a division of 08/057,191, filed May 3, 1993, which is claimed to be a continuation of U.S. Application 07/827,844, filed January 28, 1992, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988, which is claimed to be a continuation-in-part of U.S. Application 06/848,733, filed April 4, 1986, which is claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

January 6, 1995 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray filed U.S. Application 08/369,835, entitled "Synthetic Insecticidal Crystal Protein Gene" (assignment to Mycogen Plant Science, Inc., recorded April 1, 1993), which is claimed to be a continuation-in-part of 08/057,191, filed May 3, 1993, which is claimed to be a continuation of U.S. Application 07/827,844, filed January 28, 1992, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988, which is claimed

Interference 103,781

to be a continuation-in-part of U.S. Application 06/848,733, filed April 4, 1986, which is claimed to be a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

January 10, 1995 - involved U.S. Patent 5,380,831 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray, U.S. Application 08/057,191, filed May 3, 1993.

May 3, 1995 - David A. Fischhoff and Frederick J. Perlak, filed involved U.S. Application 08/434,105 entitled "Synthetic Plant Genes And Method For Preparation" (assignment to Monsanto Technology LLC recorded June 13, 2001), which is claimed to be a divisional of U.S. Application 07/959,506, filed October 9, 1992, which is claimed to be a continuation of U.S. Application 07/476,661, filed February 12, 1990, which is claimed to be a continuation-in-part of U.S. Application 07/315,355, filed February 24, 1989.

May 19, 1996 - U.S. Patent 5,500,365 issued from David A. Fischhoff and Frederick J. Perlak, U.S. Application 07/959,506, filed October 9, 1992.

August 29, 1996 - Michael J. Adang and Elizabeth E. Murray filed U.S. Application 08/705,438, entitled "Synthetic Insecticidal Crystal Protein Gene Having A Modified Frequency Of Codon Usage" (assigned to Mycogen Plant Science, Inc.), which is

Interference 103,781

claimed to be a division of U.S. Application 08/369,835, filed January 6, 1995 (now U.S. Patent 5,567,600), which is claimed to be a continuation-in-part of 08/057,191, filed May 3, 1993 (now U.S. Patent 5,380,831), which is claimed to be a continuation of U.S. Application 07/827,844, filed January 28, 1992, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988.

August 29, 1996 - Michael J. Adang and Elizabeth E. Murray filed U.S. Application 08/704,966, entitled "Transgenic Plants Comprising Synthetic Insecticidal Crystal Protein Gene Having A Modified Frequency Of Codon Usage" (assigned to Mycogen Plant Science, Inc.), which is claimed to be a division of U.S. Application 08/369,839, filed January 6, 1995 (now U.S. Patent 5,567,862), which is claimed to be a continuation-in-part of 08/057,191, filed May 3, 1993 (now U.S. Patent 5,380,831), which is claimed to be a continuation of U.S. Application 07/827,844, filed January 28, 1992, which is claimed to be a continuation-in-part of U.S. Application 07/242,482, filed September 9, 1988.

October 22, 1996 - U.S. Patent 5,567,600 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray, U.S. Application 08/369,835, filed June 6, 1995, including a disclaimer of the terminal portion of the

Interference 103,781

patent extending beyond the expiration date of U.S. Patent 5,380,831.

October 22, 1996 - U.S. Patent 5,567,862 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo and Elizabeth E. Murray, U.S. Application 08/369,839, filed June 6, 1995.

November 7, 1996 - Interference 103,781 was declared essentially as follows (Paper No. 2):

JUNIOR PARTY APPLICATION

Named Inventors: Kenneth A. Barton and Michael J. Miller

Application: Application 07/827,906, filed January 30, 1992

Title: Improved Expression of Genes in Plants

Assignee: None (assignment to Monsanto Company recorded October 15, 1996; assignment to Monsanto Technology LLC recorded June 13, 2001)

Accorded benefit for the purpose of priority of: Application 07/390,561, filed August 7, 1989

JUNIOR PARTY APPLICATION

Named Inventors: David A. Fischhoff and Frederick J. Perlak

Application: Application 08/434,105, filed May 3, 1995

Title: Synthetic Plant Genes and Method for Preparation

Assignee: None (assignment to Monsanto Technology LLC recorded June 13, 2001)

Accorded benefit for the purpose of priority of: Application 07/959,506, filed October 9, 1992, now U.S. Patent 5,500,365, issued March 3, 1996; Application 07/476,661, filed February 12, 1990, now abandoned; and Application 07/315,355, filed February 24, 1989, now abandoned

SENIOR PARTY PATENT

Named Inventors: Michael J. Adang, Thomas A. Rocheleau, Donald J. Merlo and Elizabeth E. Murray

Application: Application 08/057,191, filed May 3, 1993, now U.S. Patent 5,380,831, issued January 10, 1995

Title: Synthetic Insecticidal Crystal Protein Gene

Assignee: Mycogen Plant Science, Inc. (Paper No. 13)

Accorded benefit for the purpose of priority of: Applications 07/827,844, filed January 28, 1992, now abandoned, and Application 07/242,482, filed September 9, 1988, now abandoned

Count 1

A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

a) analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, or

b) analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence.

The claims of the parties which correspond to this count are:

Barton et al.:       Claims 1-4, 7, and 15-22

Fischhoff et al.:    Claims 3, 5, and 39-43

Adang et al.:       Claims 1-14.

December 12, 1996 - An administrative patent judge (APJ) entered an Order to Show Cause stating (Paper No. 11, pp. 1-2, bridging para.):

In view of the common ownership by Monsanto Company of the Barton application and the Fischhoff application, the junior party Barton is ordered to show cause why judgement should not be entered against him within 30 days from the date of this order. Monsanto Company, as the assignee of both Barton and Fischhoff, may name the prior inventor in response to this order. Cf. M.P.E.P. 2302.

January 17, 1997 - The APJ ordered Monsanto Company "to name the prior inventor of count 1 . . . . In the event Monsanto makes no election, judgment will be entered against junior party Barton" (Paper No. 29, p. 3).

February 3, 1997 - Junior Party Barton et al. (hereafter Barton) petitioned the Commissioner under 37 CFR § 1.644(a)(1)

Interference 103,781

to reverse or postpone the APJ's January 17, 1997 order (Paper No. 35).

March 26, 1997 - Barton's February 3, 1997, petition was denied (Paper No. 38).

June 19, 1997 - The Board of Patent Appeals and Interferences (hereafter Board) entered the following judgment (Paper No. 53):

Whereas Monsanto, the common assignee of the Barton et al. and Fischhoff et al. applications has named the party Fischhoff et al. as the prior inventor of count 1, pursuant to 37 CFR 1.602(a) and 1.610(e) judgement is hereby entered against Barton et al. as to the subject matter of count 1. Accordingly, Kenneth A. Barton and Michael J. Miller are not entitled to a patent containing Claims 1-4, 7, and 15-22 corresponding to count 1. The interference will continue as Fischhoff et al. v. Adang et al.

June 27, 1997 - Barton filed notice under 35 U.S.C. §§ 141 and 142 of appeal to the U.S. Court of Appeals for the Federal Circuit from the judgment of the Board of Patent Appeals and Interferences entered June 17, 1997 (Paper No. 55).

February 5, 1998 - The U.S. District Court for the District of Delaware entered a judgment (Mycogen Plant Science, Inc. v. Monsanto Co., No. 96-505 (D. Del. Feb. 5, 1998)) in a suit brought by Mycogen Plant Science, Inc., and Agrigenetics Inc. against Monsanto Co., DeKalb Genetics Corp., and Delta and Pine Land Co. for infringement of two Mycogen patents (Adang et al., U.S. Patent 5,567,862, entitled "Synthetic Insecticidal Crystal

Interference 103,781

Protein Gene," which issued October 22, 1996, from U.S. Application 08/369,839, filed January 6, 1995, and Adang et al., U.S. Patent 5,567,600, entitled "Synthetic Insecticidal Crystal Protein Gene," which issued October 22, 1996, from U.S. Application 08/369,835, filed January 6, 1995). A jury rendered a verdict that (1) defendants' products did not literally infringe any of the contested claims of Mycogen's patents, and (2) all of the contested claims of Mycogen's patents are invalid because Monsanto invented the subject matter thereof before the priority dates of Mycogen's patents. See the Procedural History in Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1320-1321, 58 USPQ2d 1030, 1033-1034 (Fed. Cir. 2001) (Paper No. 125).

December 9, 1998 - The Court of Appeals for the Federal Circuit reversed the Board's June 19, 1997 judgment and remanded (Paper No. 124). Barton v. Adang, 162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998) (Paper No. 118, Exhibit A).

September 8, 1999 - The U.S. District Court for the District of Delaware entered a revised order (Paper No. 125, Exh. H) and opinion ruling on post-trial motions (Paper No. 125, Exh. I) (Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. 2d 199 (D. Del. 1999)) which "granted Mycogen's motion for JMOL that Monsanto's processes and resulting products infringed . . . the

Interference 103,781

'600 and '862 patents." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1320, 58 USPQ2d at 1034 (Paper No. 146).

The district court also denied Mycogen's motion for JMOL requesting the court to set aside the jury's finding of anticipation due to prior invention by Monsanto.

The district court granted Monsanto's motion for JMOL holding that the claims of the '600 and '862 patents were invalid for lack of enablement pursuant to 35 U.S.C. § 112. . . .

Id. at 1321, 58 USPQ2d at 1034 (Paper No. 146).

November 10, 1999 - In a suit brought by Mycogen Plant Science, Inc. and Agrigenetics Inc. against Monsanto Company for infringement of plaintiff's patent (Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, from U.S. Application 08/057,191, filed May 3, 1993), the U.S. District Court for the Southern District of California entered an order (Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A) which granted defendant's motion for summary judgment that Claims 1-12 of Mycogen's '831 patent are invalid under 35 U.S.C. § 102(g) and/or § 103 because Monsanto invented the subject matter thereof before Mycogen, as determined by the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199 (D. Del. 1999), which was affirmed in Mycogen Plant Sci., Inc. v. Monsanto Inc., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), and denied defendant's motion for summary judgment that the

Interference 103,781

contested claims of Mycogen's '831 patent are invalid for noncompliance with the enablement requirement of the first paragraph of 35 U.S.C. § 112 as moot (Paper No. 127, Exh. A).

January 18, 2000 - U.S. patent 6,015,891 issued from Michael J. Adang and Elizabeth E. Murray, U.S. Application 08/705,438, filed August 29, 1996, subject to disclaimers of its term extending beyond the statutory expiration dates of Adang et al., U.S. Patent 5,567,600, issued October 22, 1996, and Adang et al., U.S. Patent 5,380,831, issued January 10, 1995.<sup>1</sup>

---

<sup>1</sup> But for prior issued patents identified in the terminal disclaimers entered as Paper No. 23 in U.S. patent 6,015,891 and Paper No. 25 in U.S. Patent 6,013,523, both disclaimers read:

The owner of 100% interest in the instant application, Mycogen Plant Science, Inc., hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 for U.S. Patent No . . . issued on . . . .

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of U.S. Patent No . . . in the event that any of the . . . patents: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term.

Interference 103,781

January 18, 2000 - U.S. patent 6,013,523 issued from Michael J. Adang and Elizabeth E. Murray, U.S. Application 08/704,966, filed August 29, 1996, subject to a disclaimer of its term extending beyond the statutory expiration date of Adang et al., U.S. Patent 5,567,862, issued October 22, 1996.

March 12, 2001 - On appeal from the decision of the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199 (D. Del. 1999), the U.S. Court of Appeals for the Federal Circuit:

. . . affirm[ed] the verdict of noninfringement based on patent invalidity due to prior invention pursuant to 35 U.S.C. § 102(g). This makes it unnecessary to address the finding of lack of enablement pursuant to 35 U.S.C. § 112.

Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1320, 58 USPQ2d at 1033 (Paper No. 146).

May 30, 2001 - On appeal from the decision of the U.S. District Court for the Southern District of California in Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A), the U.S. Court of Appeals for the Federal Circuit affirmed-in-part, reversed-in-part, and remanded. Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 1306, 58 USPQ2d 1891, 1892-1893 (Fed. Cir. 2001). The Federal Circuit concluded at 1309, 58 USPQ2d at 1893, that:

. . . the district court improperly resolved disputed questions of material fact pertaining to the issue of

prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding.

Id. at 1310, 58 USPQ2d at 1894, the Federal Circuit explained:

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention [claimed in the Mycogen's '831 patent] to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen was the first to conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

2. Outstanding requests and motions

A. Adang's Preliminary Motion 1 (Paper No. 45)

By Adang's Preliminary Motion 1 (Paper No. 45), Adang moves under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by substituting Proposed Substitute Count 2 for existing Count 1.

Fischhoff's Opposition (Paper No. 58)

Adang's Reply (Paper No. 96)

B. Adang's Preliminary Motion 2 (Paper No. 46)

By Adang's Preliminary Motion 2 (Paper No. 46), Adang moves under 37 CFR § 1.633(f) for benefit of the January 28, 1992,

Interference 103,781

filin g date of U.S. Application 07/827,844, and the September 9, 1988 filing date of U.S. Application 07/242,482, for Proposed Substitute Count 2 of Adang's Preliminary Motion 1 (Paper No. 45).

Fischhoff's response (Paper No. 59)  
Adang's Reply (Paper No. 97)

C. Adang's Contingent Preliminary Motion 3 (Paper No. 47)

By Adang's Contingent Preliminary Motion 3 (Paper No. 47), Adang moves under 37 CFR § 1.633(a) for judgment that Claims 3, 5, and 39-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, all Fischhoff's claims designated as corresponding to the interference count, are unpatentable under 35 U.S.C. § 102(g) over at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count, or under 35 U.S.C. § 103 in view of prior art including at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count. The motion presumes that party Barton has been determined to be, or Monsanto Technology LLC, the assignee of both of Fischhoff's and Barton's involved applications, has elected to designate Barton as, first to invent the subject matter defined by current Count 1 as between parties Fischhoff and Barton (Paper No. 47, pp. 1-2). In conjunction therewith, Adang contingently moves for permission to seek

Interference 103,781

deposition and documentary discovery relevant to the determination and/or election of Barton as first to invent the subject matter defined by the count as between Fischhoff and Barton (Paper No. 47, p. 2).

Fischhoff's Opposition (Paper No. 62)  
Adang's Reply (Paper No. 98)

D. Fischhoff's First 37 CFR 1.642 Request (Paper No. 78)

Fischhoff requests that the APJ exercise his discretion under 37 CFR § 1.642 to add commonly assigned Adang et al., U.S. Patent 5,567,600 (Fischhoff Exhibit 37 (FX 37)), issued October 22, 1996, to this interference, designate all twenty-four claims thereof as corresponding to the count, and set an additional preliminary motion period for the parties to file motions relative to the newly added patent (Paper No. 78, p. 1).

Adang's Opposition (Paper No. 63)  
Fischhoff's Reply (Paper No. 102)

E. Fischhoff's Second 37 CFR 1.642 Request (Paper No. 79)

Fischhoff requests that the APJ exercise his discretion under 37 CFR § 1.642 to add commonly assigned Adang et al., U.S. Patent 5,567,862 (FX 3), issued October 22, 1996, to this interference, designate all twenty-four claims thereof as corresponding to the count, and set an additional preliminary motion period for the parties to file motions relative to the newly added patent (Paper No. 79, p. 1).

Interference 103,781

Adang's Opposition (Paper No. 64)  
Fischhoff's Reply (Paper No. 103)

F. Fischhoff's Preliminary Motion 3 (Paper No. 80)

By Fischhoff's Preliminary Motion 3 (Paper No. 80), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 112, second paragraph (Paper No. 80, p. 1).

Adang's Opposition (Paper No. 65)  
Fischhoff's Reply (Paper No. 104)

G. Fischhoff's Preliminary Motion 4 (Paper No. 81)

By Fischhoff's Preliminary Motion 4 (Paper No. 81), Fischhoff moves under 37 CFR § 1.633(c)(1) to redefine the subject matter of this interference by substituting any one of Fischhoff's Proposed Counts 2, 3 and 4 for original Count 1 (Paper No. 81, p. 1).

Adang's Opposition (Paper No. 69)  
Fischhoff's Reply (Paper No. 108)

H. Fischhoff's Preliminary Motion 5 (Paper No. 82)

By Fischhoff's Preliminary Motion 5 (Paper No. 82), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 112, first paragraph (enablement requirement) (Paper N. 82, p. 1).

Adang's Opposition (Paper No. 66)  
Fischhoff's Reply (Paper No. 105)

I. Adang's 37 CFR § 635 Motion For Order Implementing the CAFC Decision In Barton v. Adang (Paper No. 116)

Adang moves under 37 CFR § 1.635 (Paper No. 116) for an order implementing the decision in Barton v. Adang, 162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998) (Paper No. 118, Exhibit A).

Joint Opposition Fischhoff and Barton (Paper No. 119)  
Adang's Reply (Paper No. 121)

J. Fischhoff's Preliminary Motion 6 (Paper No. 83)

By Fischhoff's Preliminary Motion 6 (Paper No. 83), Fischhoff moves under 37 CFR § 1.633(c)(2) to redefine the subject matter of the interference by adding proposed Claims 44 and 45 to Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995 (Paper No. 84), and designating the new claims as corresponding to the count (Paper 83, pa. 1).

K. Fischhoff's Preliminary Motion 7 (Paper No. 85)

By Fischhoff's Preliminary Motion 7 (Paper No. 85), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 102 or § 103 (Paper No. 85, p. 1).

Adang's Opposition (Paper No. 68)  
Fischhoff's Reply (Paper No. 107)

Interference 103,781

L. Fischhoff's Preliminary Motion 8 (Paper No. 86)

By Fischhoff's Preliminary Motion 8 (Paper No. 86),

Fischhoff moves under 37 CFR § 1.633(f) to be accorded benefit of the October 9, 1992, filing date of Fischhoff's U.S. Application 07/959,506; the February 12, 1990, filing date of Fischhoff's U.S. Application 07/476,661; and the February 24, 1989, filing date of U.S. Application 07/315,355, for Fischhoff's Proposed Counts 2, 3, and 4 (Fischhoff's Preliminary Motion 4, Paper No. 81) (Paper No. 86, p. 1).

M. Fischhoff's Preliminary Motion 9 (Paper No. 87)

By Fischhoff's Preliminary Motion 9 (Paper No. 87), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, are unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement) (Paper No. 87, p. 1).

Adang's Opposition (Paper No. 67)  
Fischhoff's Reply (Paper No. 106)

N. Fischhoff's Preliminary Motion 10 (Paper No. 88)

By Fischhoff's Preliminary Motion No. 10, Fischhoff moves under 37 CFR § 1.633(c)(4) to redefine the subject matter of the interference by designating (1) Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and (2) Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11),

Interference 103,781

issued January 10, 1995, as not corresponding to the count (Paper No. 88, p. 1).

Adang's Opposition (Paper No. 70)  
Fischhoff's Reply (Paper No. 109)

O. Fischhoff's Preliminary Motion 11 (Paper No. 89)

By Fischhoff's Preliminary Motion 11 (Paper No. 89), Fischhoff moves under 37 CFR § 1.633(c)(2), contingent on granting Fischhoff's Second 37 CFR § 642 Request (Paper No. 79), to redefine the subject matter of the interference by adding proposed Claims 46 to Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995 (Paper No. 90), and designating the new claim as corresponding to the count (Paper No. 89, p. 1).

P. Fischhoff's Preliminary Motion 12 (Paper No. 60)

By Fischhoff's Preliminary Motion 12 (Paper No. 60), Fischhoff moves, contingent upon the granting of Adang's Preliminary Motion 1 (Paper No. 45), for benefit under 37 CFR § 1.633(f) of the October 9, 1992, filing date of Fischhoff's U.S. Application 07/959,506, the February 12, 1990, filing date of Fischhoff's U.S. Application 07/476,661, and the February 25, 1989, filing date of Fischhoff's U.S. Application 07/315,355, for subject matter defined by Adang's Proposed Substitute Count 2.

Q. Fischhoff's 37 CFR § 1.641(a) Request (Paper No. 110)

Fischhoff requests that the APJ exercise his discretion under 37 CFR § 1.641(a), notify the parties that Claims 1-12 of

Interference 103,781

Adang's U.S. Patent 5,380,831, issued January 10, 1995, appear to be unpatentable under 35 U.S.C. § 112, first paragraph (best mode requirement), and set a time period for the parties to take testimony and present related evidence and argument (Paper No. 110, p. 2, para. I).

Adang's Response (Paper No. 111)

R. Fischhoff's 37 CFR § 1.635 Motion  
For Temporary Stay of Interference  
Under 37 CFR § 1.645(d) (Paper No. 118)

Fischhoff moves under 37 CFR § 1.635 for an order temporarily staying the interference proceedings under 37 CFR § 1.645(d) in anticipation of an impending decision of the U.S. District Court for the Southern District of California "on a motion for summary judgment that the claims of . . . Adang's . . . U.S. Patent No. 5,380,831 are invalid under 35 U.S.C. § 102(g) because of prior invention by . . . Fischhoff . . ." (Paper No. 118, p. 2, para. 1).

Adang's Opposition (Paper No. 120)

Fischhoff's Reply (Paper No. 122)

Fischhoff's Supplement To Motion (Paper No. 125)

Adang's Opposition To Supplement (Paper No. 126)

S. Fischhoff's 37 CFR § 1.635 Motion  
For Temporary Stay of Interference  
Under 37 CFR § 1.645(d) (Paper No. 127)

Fischhoff moves under 37 CFR § 1.635 for an order temporarily staying the interference proceedings under 37 CFR § 1.645(d) pending a decision on appeal to the Federal Circuit of

a decision of the U.S. District Court for the Southern District of California granting Monsanto's motion for summary judgment that claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. § 102(g) over the prior invention of Fischhoff (Paper No. 127, p. 2, para. I).

Adang's Opposition (Paper No. 128)  
Fischhoff's Reply (Paper No. 132)

3. Decisions on Outstanding Requests and Motions

"A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion. 37 CFR § 1.637(a).

A. Adang's Preliminary Motion 1 (Paper No. 45)

Adang moves under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by replacing existing Count 1 with Proposed Substitute Count 2. Existing Count 1 reads (Paper No. 45, p. 3; Paper No. 2):

Count 1

A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

a) analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, or

b) analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal

protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence.

Proposed Substitute Count 2 reads (Paper No. 45, p. 2):

Proposed Substitute Count 2

A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence;

or

A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin,

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, and

further comprising the step of modifying a portion of said coding sequence to eliminate plant polyadenylation signals.

Adang submits Proposed Substitute Count 2 to eliminate the possibility that "the analyzing step in part b) of the current

count could be incorrectly interpreted as analyzing only for the presence of polyadenylation signals" (Paper No. 45, p. 8, last complete sentence). Adang explains (Paper No. 45, p. 8, second full para.):

Unfortunately, part b) of the current count, which uses the language of Fischhoff's claim 39, recites both the claim 1 step of "modifying" to yield a modified sequence which contains a greater number of codons preferred by the intended plant host and the claim 4 step of "modifying" to eliminate plant polyadenylation sequences as a single step. As a result, the single step of part b) of the current count could be incorrectly interpreted as analyzing for any characteristic that would give the combined result of having a greater number of codons preferred by the intended plant host and eliminating plant polyadenylation signals.

The steps of the current count are not open to the interpretation Adang contemplates for two reasons. First, the alternative process defined by part b) of the current count more particularly comprises the step of "modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence" (emphasis added). When all the language of the current count is considered, the analyzing step of the process comprising part b) must comprise separate analyses of the coding sequence of a Bt gene both (1) for plant codon preferences and (2) for polyadenylation signals, and the modifying step of the process comprising part b) must comprise

Interference 103,781

separate modifications of a portion of the coding sequence to yield a modified sequence which contains (1) a greater number of codons preferred by the intended plant host than did said coding sequence, and (2) fewer polyadenylation signals than said coding sequence. Relative to the coding sequence of the Bt gene analyzed, reduction in the number of polyadenylation signals present in the coding sequence cannot simultaneously result in a greater number of codons preferred by the intended plant host relative to the number of codons preferred by the intended plant host present in the originally analyzed Bt coding sequence.

The above interpretation of the current count is consistent with the interpretations of substantially identical language in the claims of Adang's U.S. Patents 5,567,600 and 5,567,862, both issued October 22, 1995, and the parent thereof, Adang's involved U.S. Patent 5,380,831, issued January 10, 1995, by the U.S. District Court for the District of Delaware. See the district court's claim interpretation in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199, 215 (D. Del. 1999), affirmed on review by the Federal Circuit in Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1326-1327, 58 USPQ2d 1030, 1038-1039 (Fed. Cir. 2001):

Mycogen contests a portion of the district court's claim construction. Specifically, Mycogen contends that the district court's definition of the "greater number of codons preferred" language in independent claims 1,

2, 13 and 14 of the '600 patent is erroneous. However, the claim construction issue here relates to both the '600 and the '862 patent, as well as the original '831 parent patent, as all three patents contain claims that use the language disputed herein. Claim 1 of the '600 patent is representative, and it reads as follows:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:
  - (a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;
  - (b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in the codon positions II and III in a region between plant polyadenylation signals in said coding sequence;
  - (c) inserting said modified sequence into the genome of a plant cell; and
  - (d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 31, lines 37-57 (emphasis added).

In Mycogen, the district court held that:

The phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host,

and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

61 F.Supp.2d at 215. . . .

Ultimately, the Federal Circuit said, Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1329-1330, 58 USPQ2d at 1041:

[T]runcation could not satisfy the district court's definition of the claim 1 "greater number" definition, because it would not result in a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host. . . .

. . . Thus, the district court's claim construction regarding the "greater number of codons preferred" limitation was correct.

The parties present different views of the clarity of the language of current Count 1 relative to the clarity of the language of Proposed Substitute Count 2 and the scope of the subject matter encompassed by each count. However, the issues raised are more appropriately considered in the context of the parties' motions for judgment on the patentability of their claims designated as corresponding to the interference count under 35 U.S.C. § 112, second paragraph. Suffice it to say, the reasons Adang presents for redefining the interfering subject matter by replacing current Count 1 with Proposed Substitute Count 2 are based on an interpretation of the language of current Count 1 which the Federal Circuit has determined is incorrect as a matter of law.

Adang has not shown that it is entitled to the relief requested. Accordingly, Adang's Preliminary Motion 1 (Paper No. 45) is DENIED.<sup>2</sup>

B. Adang's Preliminary Motion 2 (Paper No. 46)

Adang's Preliminary Motion 2 (Paper No. 46) under 37 CFR § 1.633(f) to be accorded benefit of the filing dates of U.S. Applications 07/827,844 and 07/242,482 for subject matter of Proposed Substitute Count 2 is contingent upon Adang's Preliminary Motion 1 (Paper No. 45) under 37 CFR § 1.633(c)(1) to redefine the subject matter of this interference by replacing existing Count 1 with Proposed Substitute Count 2 being granted. Since Adang's Preliminary Motion 1 has been denied, Adang's Preliminary Motion 2 is DISMISSED.

C. Adang's Contingent Preliminary Motion 3 (Paper No. 47)

Barton v. Adang, 162 F.3d 1140, 1146, 49 USPQ2d 1128, 1134 (Fed. Cir. 1998) (Paper No. 118, Exhibit A) held that Monsanto Company had shown good cause why (1) it should not have been

---

<sup>2</sup> Given that the Delaware district court interpreted the phrase "greater number of codons preferred" appearing in many, but not all, of the claims of Mycogen's U.S. Patents 5,567,600 and 5,567,862 (the phrase also appears in Claim 1 of Mycogen's U.S. Patent 5,380,831 and Count 1 of this interference recites the language of Claim 1 of U.S. Patent 5,380,831), the issue yet to be considered is whether the subject matter of the interference count should be redefined utilizing the language of Claim 11 of U.S. Patent 5,380,831. This issue is raised by Fischhoff's Preliminary Motion 4 (Paper No. 81).

forced to elect the prior inventor of Count 1 as between Fischhoff and Barton before the subject matter defined by the interference count is finalized, and (2) Barton should not have been prematurely dismissed as a party to this interference:

[A]t the time that Monsanto was forced to make an election between the Barton et al. and the Fischhoff et al. applications, it was not clear what the content of the final count would be or what proofs on dates of conception and reduction to practice Adang et al. would seek to establish. Also, if the final count as decided by the Board excluded subject matter disclosed in Barton et al., but not Fischhoff et al., Monsanto loses arguably patentable subject matter by early dismissal of Barton et al.

At this stage of the proceedings, Monsanto could not determine which application, either Barton et al. or Fischhoff et al., would be the best evidence to establish priority. We hold that Monsanto has shown "good cause" to continue the interference on both its applications until the preliminary motions to finalize the count are decided by the Board and discovery is complete.

Because Monsanto Company was improperly ordered to elect the prior inventor of Count 1 as between Barton and Fischhoff before the interference count was finalized, neither Fischhoff's nor Barton's claims designated as corresponding to Count 1 may be rejected under 35 U.S.C. § 102(g)/103 based on a forced election of the prior inventor of Count 1 by Monsanto Company at a time during the proceedings when "Monsanto could not determine which application, either Barton et al. or Fischhoff et al., would be the best evidence to establish priority." Id. Moreover, even if

Interference 103,781

Monsanto's forced election of the prior inventor of Count 1 as between Barton and Fischhoff could be basis for rejecting the nonelected party's claims under 35 U.S.C. § 102(g)/103,

Monsanto's election of Fischhoff as the prior inventor of Count 1 most certainly does not support Adang's Contingent Preliminary Motion 3 under 37 CFR § 1.633(a) for a judgment that Fischhoff's claims designated as corresponding to Count 1 are unpatentable under 35 U.S.C. § 102(g)/103 over Barton's claims designated as corresponding to Count 1.

Because the Federal Circuit directed this interference proceeding to continue with both Fischhoff and Barton as parties "until the preliminary motions to finalize the count are decided by the Board and discovery is complete," Barton v. Adang, 162 F.3d at 1146, 49 USPQ2d at 1134, the discovery Adang requests is here, and is generally, inappropriate before the preliminary motion stage of the interference proceeding has been completed. Accordingly, Adang's Contingent Preliminary Motion 3 and the order for discovery Adang requests (Paper No. 47) are DENIED.

D. Fischhoff's First and Second 37 CFR § 1.642 Requests (Paper Nos. 78 & 79)

Fischhoff (Monsanto) asks the APJ to exercise his discretion under 37 CFR § 1.642 to (1) add Adang's (Mycogen's) U.S. Patent 5,567,600 (FX 37) and U.S. Patent 5,567,862 (FX 3), both issued October 22, 1996, to this interference, (2) designate all claims

Interference 103,781

of each patent as corresponding to the count, and (3) set an additional preliminary motion period for the parties to file motions relative to the newly added patents (Paper No. 78, p. 1; Paper No. 79, p. 1). However, on September 8, 1999, the U.S. District Court for the District of Delaware held that the claims of both Mycogen's U.S. Patent 5,567,600 (FX 37) and Mycogen's U.S. Patent 5,567,862 (FX 3) are invalid as unpatentable (1) under 35 U.S.C. § 102(g)/103 due to prior invention of the subject matter thereof by Monsanto, and (2) under 35 U.S.C. § 112, first paragraph, as based on a nonenabling disclosure.

Mycogen Plant Science, Inc. v. Monsanto Co., 61 F. Supp.2d 199 (D. Del. 1999). The district court's decision that the claims of Mycogen's U.S. Patents 5,567,600 (FX 37) and 5,567,862 (FX 3) are invalid as unpatentable under 35 U.S.C. § 102(g)/103 was affirmed on appeal to the Federal Circuit. Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1320, 58 USPQ2d 1030, 1034 (Fed. Cir. 2001) (Paper No. 146).

The parties to this interference have not discussed the Delaware district court's conclusions that the claims of Mycogen's U.S. Patent 5,567,600 (FX 37) and the claims of Mycogen's U.S. Patent 5,567,862 (FX 3) are invalid as unpatentable under 35 U.S.C. § 102(g)/103 because of prior invention by Monsanto or as unpatentable under 35 U.S.C. § 112,

Interference 103,781

first paragraph (nonenablement). Mycogen has neither shown nor argued that the Delaware district court's conclusions are incorrect. Moreover, the Federal Circuit affirmed the Delaware district court's holding that the claims of Mycogen's patents are invalid under 35 U.S.C. § 102(g) over Monsanto's prior invention. Accordingly, Fischhoff's requests to redefine the interfering subject matter by adding Mycogen's U.S. Patents 5,567,600 (FX 37) and 5,567,862 (FX 3) to this interference and designating the claims of those patents as corresponding to the count are DISMISSED.

There is a related matter. On January 18, 2000, U.S. Patent 6,015,891 (Appendix A) issued from Michael J. Adang and Elizabeth E. Murray, U.S. Application 08/705,438, filed August 29, 1996, including a terminal disclaimer of its term which extends beyond the statutory expiration dates of Mycogen's U.S. Patent 5,567,600 and U.S. Patent 5,380,831, issued January 10, 1995, and U.S. Patent 6,013,523 (Appendix B) issued from Michael J. Adang and Elizabeth E. Murray, U.S. Application 08/704,966, filed August 29, 1996, including a terminal disclaimer of its term which extends beyond the statutory expiration date of Mycogen's U.S. Patent 5,567,862. To completely resolve all patentability issues concerning what appears to be claims drawn to the "same patentable invention" as the claims presently designated as

corresponding to the count and priority of invention for the subject matter defined by the count as between the parties to this interference, a comparison of the representative method and gene claims presented in Mycogen's U.S. Patents 5,380,831, 5,567,600, 5,567,862, 6,013,523, and 6,015,891, is in order.

Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831 read:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence.

11. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed.

Claim 1 of Mycogen's U.S. Patent 6,013,523 reads:

1. A descendant plant cell comprising a pesticidal protein toxin encoded by a synthetic Bacillus thuringiensis (B.t.) gene, said cell produced by the process of:

selecting a B.t. pesticidal protein toxin desired to be expressed in a plant cell;

obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene;

using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage of the plant in which it is to be expressed than did the native B.t. coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence;

obtaining a synthetic B.t. gene comprising a coding region comprising said modified coding sequence wherein said coding region is under the control of a plant-expressible promoter;

introducing said synthetic B.t. gene into a plant cell;

culturing said cell to obtain descendant plant cells or plants comprising descendant plant cells, said descendant plant cells comprising said synthetic B.t. gene; and

establishing that said synthetic B.t. gene is expressed in said descendant plant cells.

Claims 1 and 4 of Mycogen's U.S. Patent 6,015,891:

1. A synthetic Bacillus thuringiensis (B.t.) gene which is expressed in descendant plant cells and encodes a pesticidal protein toxin, wherein said synthetic B.t. gene is produced by the process of:

selecting a B.t. pesticidal protein toxin desired to be expressed in a plant cell;

obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene;

using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage

of the plant cell in which it is to be expressed than did the native B.t. coding sequence encoding said protein toxin, said modified coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence;

obtaining a synthetic B.t. gene comprising a coding region comprising said modified coding sequence wherein said coding region is under the control of a plant-expressible promoter;

introducing said synthetic B.t. gene into a plant cell;

culturing said cell to obtain descendant plant cells or plants comprising descendant plant cells, said descendant plant cells comprising said synthetic B.t. gene; and

establishing that said synthetic B.t. gene is expressed in said descendant plant cells.

4. A method of designing a synthetic Bacillus thuringiensis (B.t.) gene which is expressed in descendant plant cells, comprising the steps of:

selecting a B.t. pesticidal protein toxin desired to be expressed in a plant cell;

obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene;

using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage of the plant cell in which it is to be expressed than did the native B.t. coding sequence encoding said protein toxin, said modified coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence;

obtaining a synthetic B.t. gene comprising a coding region comprising said modified coding sequence wherein said coding region is under the control of a plant-expressible promoter;

introducing said synthetic B.t. gene into a plant cell;

culturing said cell to obtain descendant plant cells, said descendant plant cells comprising said synthetic B.t. gene; and

establishing that said synthetic B.t. gene is expressed in said descendant plant cells.

Claims 1, 2, 7, 8, 13, 14, 19 and 20 of Mycogen's U.S. Patent 5,567,600 (FX 37), which were determined by the Delaware district court to be invalid, read:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

2. A DNA coding sequence produced by:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal

protein toxin; and

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence.

7. A method of designing a synthesis Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

8. A DNA coding sequence produced by:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin; and

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon

usage of the plant in which it is to be expressed than did said coding sequence, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence.

13. A method of designing a synthesis Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified sequence than in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthesis Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

14. A DNA coding sequence produced by:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin; and

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified sequence than in said coding sequence.

19. A method of designing a synthesis Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed than did said coding sequence prior to modification, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified sequence than in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

20. A DNA coding sequence produced by:

(a) analog the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin; and

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed than did said coding sequence, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified sequence than in said coding sequence.

Claims 1, 6, 7, 12, 13, 18, 19, and 24 of U.S. Patent 5,567,862 (FX 3), read:

1. A plant cell comprising a heterologous modified structural gene derived from a Bacillus thuringiensis gene encoding a pesticidal protein toxin, said plant cell produced by the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) a portion of said coding sequence to yield a modified structural gene which contains a greater number of codons preferred by said plant cell than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

6. A method of producing a pesticidal protein comprising the steps of:

(a) introducing into a host plant cell a heterologous modified structural gene derived from a Bacillus thuringiensis gene wherein the DNA coding sequence of the Bacillus thuringiensis gene has been modified to contain a greater number of codons preferred by said plant cell than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence, and

(b) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant

cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin

7. A plant cell comprising a heterologous modified structural gene derived from a Bacillus thuringiensis gene encoding a pesticidal protein toxin, said plant cell produced by the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of genes native to said plant cell than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified structural gene into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified gene in the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

12. A method of producing a pesticidal protein comprising the steps of

(a) introducing into a host plant cell a heterologous modified structural gene derived from a Bacillus thuringiensis gene wherein the DNA coding sequence of the Bacillus thuringiensis gene has been modified to contain a frequency of codon usage that more closely resembles the frequency of codon usage of genes native to said plant cell than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence; and

(b) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

13. A plant cell comprising a heterologous modified structural gene derived from a Bacillus thuringiensis gene encoding a pesticidal protein toxin, said plant cell produced by the steps of

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said codon sequence to yield a modified structural gene which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified structural gene than in said coding sequence;

(c) inserting said modified structural gene into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

18. A method of producing a pesticidal protein comprising the steps of

(a) introducing into a host plant cell a heterologous modified structural gene derived from a Bacillus thuringiensis gene wherein the DNA coding sequence of the Bacillus thuringiensis gene has been modified to contain a greater number of codons preferred by said plant cell than did said coding sequence prior to modification, and wherein the modification results in fewer occurrences of the sequence AATGAA in said modified structural gene than in said coding sequence; and

(b) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

19. A plant cell comprising a heterologous modified structural gene derived from a Bacillus thuringiensis gene encoding a pesticidal protein toxin, said plant cell produced by the steps of

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified structural gene which has a frequency of codon usage which more closely resembles the frequency of codon usage of genes native to said plant cell than did said coding sequence prior to modification, and wherein said modification results in fewer occurrences of the sequence AATGAA in said modified sequence than in said coding sequence;

(c) inserting said modified structural gene into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant

cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

24. A method of producing a pesticidal protein comprising the steps of

(a) introducing into a host plant cell a heterologous modified structural gene derived from a Bacillus thuringiensis gene wherein the DNA coding sequence of the Bacillus thuringiensis gene has been modified to contain a frequency of codon usage that more closely resembles the frequency of codon usage of genes native to said plant cell than did the coding

sequence prior to modification, and wherein the modification results in fewer occurrences of the sequence AATGAA in said modified structural gene than in said coding sequence; and

(b) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified structural gene in the genome of said additional plant cells, wherein said modified structural gene is expressed to produce a pesticidal protein toxin.

Claims 1, 4, and 11 of Mycogen's U.S. Patent 5,380,831 are directed to methods of designing a synthetic B.t. gene to be more highly expressed in a plant than a native B.t. gene, comprising:

- (a) analyzing the coding sequence of a native B.t. gene encoding an insecticide, and
- (b) modifying a portion of said analyzed coding sequence
  - (i) to contain a greater number of codons preferred by said plant than did the analyzed coding sequence, and/or
  - (ii) to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of said plant.

By reference to substantially the same language appearing in claims of Mycogen's U.S. Patent 5,467,600, the Federal Circuit indicated that the subject matter defined by the language of step (b)(i) above, which also appears in the process defined by Claim 1 of Mycogen's U.S. Patent 5,380,831, is either synonymous

Interference 103,781

with, of subsumed by, the language of step (b)(ii) above, which appears in the process defined by Claim 11 of Mycogen's U.S. Patent 5,380,831. In Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1327, 58 USPQ2d 1030, 1038 (Fed. Cir. 2001), the Federal Circuit quoted the following holding of the Delaware district court in reference to Claims 1, 2, 13, and 14 of Mycogen's U.S. Patent 5,567,600:

[T]he phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

Mycogen Plant Science, Inc. v. Monsanto Co., 61 F. Supp.2d 199, 215 (D. Del. 1999).

On appeal, Mycogen contested the Delaware district court's claim interpretation. See Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1326, 58 USPQ2d at 1038:

Mycogen contests a portion of the district court's claim construction. Specifically, Mycogen contends that the district court's definition of the "greater number of codons preferred" language in independent claims 1, 2, 13 and 14 of the '600 patent is erroneous. However, the claim construction issue here relates to both the '600 and the '862 patent, as well as the original '831 parent patent, as all three patents contain claims that use the language disputed herein.

The Federal Circuit stated, 243 F.3d at 1327, 58 USPQ2d at 1039:

[T]he district court's claim construction defines a "preferred codon" to be any codon that brings the modified Bt gene's codon frequency closer to that of the intended plant host.

Mycogen responded, Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1328-1329, 58 USPQ2d at 1040:

[T]he district court's definition of "greater number of codons preferred" cannot stand because it renders this phrase synonymous with the "frequency of codon usage" limitation in independent claims 7, 8, 19 and 20 of the '600 patent, thus rendering these two sets of claims identical.

The Federal Circuit held that "the district court's claim construction regarding the 'greater number of codons preferred' limitation was correct." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1330, 58 USPQ2d at 1041.

The two-step methods claimed in Mycogen's U.S. 5,380,831 are broader in scope than the four-step methods claimed in each of Mycogen's U.S. Patent 5,567,600, U.S. Patent 5,567,862, U.S. Patent 6,013,523, and U.S. Patent 6,015,891, because the claimed two-step methods "of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants" are open to the additional steps of "inserting said modified sequence into the genome of a plant cell; and . . . maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said

synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin"; e.g., Claims 1 and 7 of Mycogen's U.S. Patent 5,567,600. Thus, the Delaware district court's conclusion that the four-step methods claimed in Mycogen's U.S. Patents 5,567,600 and 5,567,862, which include the two-step methods claimed in Mycogen's U.S. Patent 5,380,831, are unpatentable under 35 U.S.C. § 102(g)/103 and/or 35 U.S.C. § 112, first paragraph (enablement requirement), does not require a conclusion that the two-step methods claimed in Mycogen's U.S. Patent 5,380,831 are unpatentable for all the same reasons. The enablement problems may stem from the added method steps. Showings required to establish priority of invention for four-step processes generally exceed showings required to establish priority of invention for at least two steps of the four-step processes. Furthermore, the Delaware district court's conclusion that claims of Mycogen's U.S. Patent 5,567,600, which are drawn to a DNA coding sequence produced by the method of Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831, are unpatentable under 35 U.S.C. § 102(g)/103 and/or 35 U.S.C. § 112, first paragraph, does not require a conclusion that method Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831 also are unpatentable under 35 U.S.C. § 102(g)/103 and/or 35 U.S.C. § 112, first paragraph, for the same reasons.

However, the conclusion that the DNA coding sequences of Claims 2 and 8 of Mycogen's U.S. Patent 5,567,600, which are produced by the methods of Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831, are directed to the "same . . . invention" as the methods of Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831, and accordingly, the "same . . . invention" as Count 1 of this interference, is inescapable because the processes defined by Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831 and the processes which define the products-by-process of Claims 2 and 8 of Mycogen's U.S. Patent 5,567,600 are identical. Moreover, the four-step processes of designing a synthetic B.t. gene to be more highly expressed in plants of Claims 1 and 7 of Mycogen's U.S. Patent 5,567,600 would have been obvious under 35 U.S.C. § 103 to persons having ordinary skill in the art in view of the two-step processes of Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831 for designing a synthetic B.t. gene to be more highly expressed in plants, because the two additional steps of the four-step processes of the '600 patent no more than generally recite the utility described for the two-step processes of the '831 patent. See 37 CFR § 1.642 and 37 CFR § 1.601(n). The product-by-process claims of Mycogen's U.S. Patent 5,567,862 are directed to the "same . . . invention" as the process claims of Mycogen's U.S. Patent 5,567,600 again because the processes

defined by the product-by-process claims and the process claims of the respective patents are identical.

Nevertheless, even though the Delaware district court held that the claims of Mycogen's U.S. Patents 5,567,600 and 5,567,862 are invalid, the claims of Mycogen's U.S. Patents 6,013,523 and 6,015,891 are presumed valid. Therefore, questions of greater import to the present interference are whether the claims of the later issued patents, which are presumed valid, are directed to the same patentable invention as Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831 and Count 1, and accordingly, whether the subject matter of the count should be redefined by (1) adding Mycogen's U.S. Patent 6,015,891 to this interference and designating Claims 1-6 thereof as corresponding to the count, and (2) adding Mycogen's U.S. Patent 6,013,523 to this interference and designating Claims 1-4 thereof as corresponding to the count.

First, the terminal portion of Mycogen's U.S. Patent 6,015,891 which extends beyond the expiration dates of Mycogen's U.S. Patents 5,567,600 and 5,380,831 has been disclaimed by Mycogen, and the terminal portion of Mycogen's U.S. Patent 6,013,523 which extends beyond the expiration date of Mycogen's U.S. Patents 5,567,862 has been disclaimed by Mycogen. Terminal disclaimers are necessitated by an examiner's rejection of claims of a later-issued, commonly assigned patent for obviousness-type

Interference 103,781

double patenting of the subject matter claimed in an earlier-issued, unexpired patent.

Second, Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1325, 58 USPQ2d at 1037, instructs:

The district court analyzed the infringement decision and stated "[f]or every one of [Monsanto's] accused genes and gene products, Mycogen presented evidence, detailed below, showing that a particular codon usage table was used to design each accused gene in a way that infringes the '600 and '862 patents. Defendants did not challenge this evidence. Mycogen, 61 F. Supp. 2d at 245.

Mycogen has established that the common analysis and modification steps of the processes claimed in Mycogen's U.S. Patent 5,567,600 and U.S. Patent 5,567,862 involve the steps of (I) "obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene," and (II) "using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage of the plant cell in which it is to be expressed than did the native B.t. coding sequence encoding said protein toxin, said modified coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence" (Mycogen's U.S. 6,015,891, Claims 1 and 4; Mycogen's U.S. 6,013,523, Claim 1). Method Claims 1 and 11 of Mycogen's U.S. 5,380,831 comprise analysis and modification steps

substantially identical to those recited in the method claims of Mycogen's U.S. Patents 5,567,600 and 5,567,862. Moreover, the specification of Mycogen's U.S. 5,380,831 teaches (col. 7, l. 1-28) (emphasis added):

Frequency of preferred codon usage refers to the preference exhibited by a specific host cell in usage of nucleotide codons to specify a given amino acid. To determine the frequency of usage of a particular codon in a gene, the number of occurrences of that codon in the gene is divided by the total number of occurrences of all codons specifying the same amino acid in the gene. Table 1, for example, gives the frequency of codon usage for Bt genes, which was obtained by analysis of four Bt genes whose sequences are publicly available. Similarly, the frequency of preferred codon usage exhibited by a host cell can be calculated by averaging frequency of preferred codon usage in a large number of genes expressed by the host cell. It is preferable that this analysis be limited to genes that are highly expressed by the host cell. Table 1 (see page 43), for example, gives the frequency of codon usage by highly expressed genes exhibited by dicotyledonous plants, and monocotyledonous plants. The dicot codon usage was calculated using 154 highly expressed coding sequences obtained from Genbank which are listed in Table 1. Monocot codon usage was calculated using 53 monocot nuclear gene coding sequences obtained from Genbank and listed in Table 1, located in Example 1.

When synthesizing a gene for improved expression in a host cell it is desirable to design the gene such that its frequency of codon usage approaches the frequency of preferred codon usage of the host cell.

Mycogen's U.S. Patent 5,380,831 expressly states (Col. 10, l. 62, to Col. 11, l. 3) (emphasis added):

For example, in preferred embodiments, the synthetic insecticidal protein is strongly expressed in dicot plants, e.g., tobacco, tomato, cotton, etc., and hence,

a synthetic gene under these conditions is designed to incorporate to advantage codons used preferentially by highly expressed dicot proteins. In embodiments where enhanced expression of insecticidal protein is desired in a monocot, codons preferred by highly expressed monocot proteins (given in Table 1) are employed in designing the synthetic gene.

See also the disclosure of Mycogen's U.S. Patent 5,380,831 at column 11, lines 27-59, with regard to preferable avoidance of the CG dinucleotide in codon positions II and III, including references to prior art disclosing the "two codon choice indices for quantifying CG and AT doublet avoidance in codon positions II and III" (col. 11, l. 38-41) calculated for the plant data presented and tabulated in Table 2 (col. 11, l. 44-59). Claim 3 of Mycogen's U.S. Patent 5,380,831 explicitly recites "the step of modifying a portion of said coding sequence to yield CG and AT doublet avoidance indices which more closely resemble those of the intended plant host" (Col. 38, l. 38-41, Claim 3).

Third, Mycogen's U.S. Patent 5,380,831 includes the following statements (Col. 14, l. 12-66; citations omitted):

The recombinant DNA molecule carrying a synthetic structural gene under promoter control can be introduced into plant tissue by any means known to those skilled in the art. The technique used for a given plant species or specific type of plant tissue depends on the known successful techniques. . . . Once introduced into the plant tissue, the expression of the structural gene may be assayed by any means known to the art, and expression may be measured as mRNA transcribed or as protein synthesized. Techniques are known for the in vitro culture of plant tissue, and in a number of cases, for regeneration of whole plants. Procedures for

transferring the introduced expression complex to commercially useful cultivars are known to those skilled in the art.

Once plant cells expressing a synthetic insecticidal structural gene under control of a plant expressible promoter are obtained, plant tissues and whole plants are then reproduced by conventional means and the introduced genes can be transferred to other strains and cultivars by conventional plant breeding techniques.

Given that Mycogen has terminally disclaimed the unexpired term of Mycogen's U.S. Patent 6,015,891 which extends beyond the expiration dates of Mycogen's U.S. Patents 5,567,600 and 5,380,831 and the unexpired term of Mycogen's U.S. Patent 6,013,523 which extends beyond the expiration date of Mycogen's U.S. Patent 5,567,862 and, presuming that the claims of Mycogen's U.S. Patent 5,567,600, U.S. Patent 5,567,862, and U.S. Patent 5,380,831 are directed to the same invention as Count 1 of this interference, it seems reasonable to conclude that the subject matter claimed of Mycogen's U.S. Patents 6,015,891 and 6,013,523 would have been obvious to persons having ordinary skill in the art in view of prior art including Claims 1 and 11 of Mycogen's U.S. Patent 5,380,831. Accordingly, arguments can be made that the claims of Mycogen's U.S. Patents 6,015,891 and 6,013,523 are directed to the "same patentable invention" as the claims in Mycogen's U.S. Patent 5,380,831 and Count 1 of this interference. Therefore, the parties should consider whether Mycogen's U.S.

Interference 103,781

Patents 6,015,891 and 6,013,523 should be added to this interference.

E. Fischhoff's Preliminary Motion 4 (Paper No. 81)

By Fischhoff's Preliminary Motion 4 (Paper No. 81), Fischhoff moves under 37 CFR § 1.633(c)(1) to redefine the interference count by substituting Proposed Count 2, 3, or 4 for existing Count 1 (Paper No. 81, p. 1). The alternatively proposed counts read as follows (Paper No. 81, pp. 14-16):

Fischhoff's Proposed Count 2

Claim 1 of the '831 patent;<sup>3</sup>

- or -

Claim 3 of the '105 application.<sup>4</sup>

---

<sup>3</sup> 1. ['831 patent] A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence.

<sup>4</sup> 3. ['105 application] A method for modifying a wild-type structural gene sequence which encodes an insecticidal protein of Bacillus thuringiensis to enhance the expression of said protein in plants which comprises:

a) removing polyadenylation signals contains [sic] in said wild-type gene while retaining a sequence which encodes said protein; and

Fischhoff's Proposed Count 3

All claims of the party Adang et al. that survive the 37 CFR 1.633(a) and 37 CFR (c)(4) motions filed by the party Fischhoff et al.;

- or -

All claims of the party Fischhoff et al. (except claim 43) that survive any 37 CFR 1.633(a) and 37 CFR (c)(4) motions filed by the party Adang et al.

Fischhoff's Proposed Count 4

A. A method of preparing a gene derived from a Bacillus thuringiensis, said method comprising the steps of:

- (a) selecting a group of genes that encode expressed proteins in a host plant;
- (b) calculating the frequency of usage for codons within the structural coding region in said group of genes;
- (c) selecting a gene derived from Bacillus thuringiensis, which encodes an insecticidal protein having an amino acid sequence;
- (d) preparing a gene encoding the same amino acid sequence as the gene selected in step (c) but which has a structural coding region with:
  - (i) a frequency of usage for codons that closely approaches the frequency of usage for codons determined in step (b);
- (e) inserting the gene obtained in step (d) into said host plant's genome; and

---

b) removing ATTAA sequences contained in said wild-type gene while retaining a sequence which encodes said protein.

(f) obtaining a transgenic plant with enhanced expression of a protein derived from a Bacillus thuringiensis;

- or -

B. A method of preparing a gene derived from a Bacillus thuringiensis, said method comprising the steps of:

- (a) selecting a gene derived from a Bacillus thuringiensis, which encodes an insecticidal protein having an amino acid sequence:
- (b) preparing a gene encoding the same amino acid sequence as the gene selected in step (a) but which has a structural coding region with:
  - (i) fewer ATTAA sequences,
  - (ii) fewer plant polyadenylation signals, and
  - (iii) lower A+T content
- (c) inserting the gene obtained in step (b) into a host plant's genome; and
- (d) obtaining a transgenic plant with enhanced expression of a protein derived from a Bacillus thuringiensis.

The phrase "greater number of codons preferred" of Claim 1 of Mycogen's U.S. 5,380,831 has been interpreted as follows by the Delaware district court in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d at 215:

[T]he phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

Interference 103,781

Given that interpretation, Fischhoff argues that existing Count 2 ought to be replaced by Fischhoff's Proposed Count 2, 3, or 4 because "Count 1 is narrower than the corresponding definition of gene modifications in Claim 3 of the '105 application" (Paper No. 81, p. 4, l. 1-3). In effect, Fischhoff argues that Fischhoff's Proposed Count 2, 3, or 4 should be substituted for existing Count 1 because the invention of Claim 3 of Fischhoff's involved U.S. Application 08/434,105 is not encompassed by, and does not correspond to, the interfering subject matter defined by existing Count 1. Whether presented in a motion under 37 CFR § 1.633(c)(4) to redefine the interfering subject matter by designating Claim 3 of the '105 application as not corresponding to the count or in a motion under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by substituting a count, the issue is the same. Presuming that Claim 3 of Fischhoff's U.S. Application 08/434,105 stands properly designated as corresponding to Count 1, the question to be asked is whether Fischhoff has provided sufficient reasons why the relief it requests should be granted?

Claim 3 of Fischhoff's involved U.S. Application 08/434,105 reads (Paper No. 81, p. 4):

3. ('105 Appl.) A method for modifying a wild-type structural gene sequence which encodes an insecticidal protein of Bacillus thuringiensis to enhance the expression of said protein in plants which comprises:

- a) removing polyadenylation signals contained in said wild-type gene while retaining a sequence which encodes said protein; and
- b) removing ATTAA sequences contained in said wild-type gene while retaining a sequence which encodes said protein.

On its face, neither the step of part a) nor the step of part b) of Claim 3 of the Fischhoff's '105 application appears to create a synthetic gene having a "higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host," the interpretation given the language "greater number of codons preferred" of Count 1 of this interference and Claim 1 of Mycogen's U.S. Patent 5,380,831 by the Delaware district court. Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), affirming Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d at 215. However, Count 1 of this interference alternatively comprises the step of "modify a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence" (Paper No. 2, Count 1b,; emphasis added).

The criteria for determining whether a claim should be designated as not corresponding to the count is presented in

Interference 103,781

37 CFR § 1.637(c)(4):

A preliminary motion seeking to designate an application or patent claim as not corresponding to the count shall:

- (i) Identify the claim and the count.
- (ii) Show that the claim does not define [sic] the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute.

Fischhoff does not dispute that Claim 5 of Fischhoff's U.S. Application 08/434,105, as amended November 29, 1995, stands properly designated as corresponding to Count 1. Claim 5 of the '105 application, as amended November 29, 1995, reads:

5. The method of Claim 3 further comprising the use of plant preferred sequences in the removal of the polyadenylation signals and ATTAA sequences.

Claim 5 of the '105 application, as originally filed, differed from Claim 5, as amended November 29, 1995, only in its dependency on original Claim 4. Claim 4 of the '105 application, as originally filed, defines the scope of the subject matter encompassed by Claim 5 designated as corresponding to Count 1.

Original Claim 4 reads:

4. A method of Claim 3 further comprising the removal of self-complementary sequences and replacement of such sequences with nonself-complementary DNA comprising preferred codons while retaining a structural gene sequence encoding said protein.

The designation of Claim 5 of the '105 application as corresponding to Count 1 is not disputed by Fischhoff. Thus, the only question to be decided is whether Claim 3 of the '105 application defines the same patentable invention as Claim 5 of the '105 application.

Claim 3 of the '105 application is directed to the same patentable invention as Claim 5 of the '105 application if the subject matter defined by Claim 3 would have been obvious under 35 U.S.C. § 103 to a person having ordinary skill in the art in view of prior art assumed to include the subject matter of Claim 5 of the '105 application. 37 CFR § 1.601(n). If it is properly dependent on Claim 3 of the '105 application, method Claim 5 of the '105 application must be construed to incorporate by reference all the process limitations of Claim 3 of the '105 application to which it refers and set forth a further limitation thereof. 35 U.S.C. § 112, fourth paragraph. Neither Fischhoff, Adang, nor ~~the~~ examiner responsible for initiating this interference rejected the patentability of Claim 5 of the '105 application under 35 U.S.C. § 112, fourth paragraph. Therefore, the conclusion is inescapable that the subject matter defined by independent Claim 3 of the '105 application would have been prima facie obvious to a person having ordinary skill in the art in view of the subject matter defined by dependent Claim 5 of the

'105 application which incorporates all the limitations of independent Claim 3 of the '105 application upon which it depends. Accordingly, Fischhoff's justification for redefining the subject matter of the interference by substituting substitute Count 2, 3, or 4 for Count 1 is undermined. Thus, Fischhoff has not met its burden to show it is entitled to the relief sought.

Mycogen also suggests that Monsanto's motion to redefine the interfering subject matter by substituting proposed Count 2, 3, or 4 for existing Count 1 is designed primarily to expand the scope of the subject matter defined by the interference count to include methods of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants comprising the steps of analyzing the coding sequence of a gene derived from B.t. which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains either (1) a greater number of codons preferred by the intended plant than did said coding sequence, (2) fewer plant polyadenylation signals than did said coding sequence, or (3) fewer ATTAA sequences than did said coding sequence. Whether or not Monsanto's aim is to expand the scope of the interfering subject matter, and concomitantly, the scope of the evidence upon which Mycogen and Monsanto may rely to show priority with respect to the same patentable invention claimed by the parties to this

interference, Monsanto's motion may be warranted if the broader scope of the interfering subject matter defined by the substitute count better defines the scope of the patentable invention contested by the parties to this interference.

Does any one of Fischhoff's Proposed Counts 2, 3, and 4 better define the scope of the interfering subject matter for which priority of invention is contested by the parties to this interference than existing Count 1? If so, then Fischhoff's motion to redefine the subject matter claimed by substituting that proposed count for existing Count 1 should be granted.

Proposed Count 4 alternatively defines methods of preparing a gene derived from B.t. which includes extraneous steps upon which the parties do not rely for patentability and language and/or terms whose meanings remain subject to interpretation; e.g., "calculating the frequency of usage for codons within the structural coding region in said group of genes" (Proposed Count 4A(b)) and "lower A+T content" (Proposed Count 4B(b)(iii)). Proposed Count 3 creates more uncertainty than certainty as to the scope of the interfering subject matter. The full scope of the subject matter defined by Proposed Count 3 must be finally resolved before the parties can determine what evidence is relevant to their respective cases for priority of invention.

On the other hand, Proposed Count 2, which is directed alternatively to Claim 1 of Mycogen's U.S. Patent 5,380,831 and Claim 3 of Monsanto's U.S. Application 08/434,104, is not only well defined, but it broadly encompasses claimed subject matter which the parties consider best representative of their inventions. Although Claim 1 of Mycogen's U.S. Patent 5,380,831 and Claim 3 of Monsanto's U.S. Application 08/434,104 do not themselves appear to be directed to the same patentable invention, Claim 4 of Mycogen's U.S. Patent 5,380,831 and Claim 5 of Monsanto's U.S. Application 08/434,104, which are designated as corresponding to Count 1 (in-part a transcription of Claim 1 of Mycogen's U.S. Patent 5,380,831), clearly define the same patentable invention. See 37 CFR § 1.601(j):

An interference-in-fact exists when at least one claim of a party that is designated to correspond to the count and at least one claim of an opponent which is designated to correspond to the count define the same patentable invention.

Nevertheless, given the Delaware district court's interpretation of language in claims of Mycogen's U.S. Patent 5,567,600 common to language in Claim 1 of Mycogen's U.S. Patent 5,380,831 in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199, 215 (D. Del. 1999), Fischhoff's Proposed Count 2 is not broad enough to encompass all claims that are patentable over the prior art and correspond to the count. See 37 CFR §§ 1.601(f) and 606.

Interference 103,781

Claims 11 and 12 of Mycogen's U.S. 5,380,831 are presumed to be patentable over the prior art and, on their face, appear to be broader in scope than the subject matter defined by either Claim 1 of Mycogen's U.S. Patent 5,380,831 or Claim 3 of Monsanto's U.S. Application 08/434,104. Accordingly, to the extent Fischhoff moves under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by substituting any one of proposed Counts 2, 3, and 4 for existing Count 1 (Paper No. 81), the motion is DENIED.

However, Fischhoff alternatively invites the APJ to substitute a count of its own construction which is not narrower in scope than any application claim that is patentable over the prior art which is designated as corresponding to the count or any patent claim designated to correspond to the count. The invitation is accepted.

It is ORDERED that Interference 103,781 is redeclared as:

JUNIOR PARTY APPLICATION (Fischhoff)

Named Inventors: Kenneth A. Barton and Michael J. Miller

Application: Application 07/827,906, filed January 30, 1992

Title: Improved Expression of Genes in Plants

Assignee: None (assignment to Monsanto Company recorded October 15, 1996; assignment to Monsanto Technology LLC recorded June 13, 2001)

Interference 103,781

Accorded benefit  
for the purpose of  
priority of: Application 07/390,561, filed August 7,  
1989

- or -

Named Inventors: David A. Fischhoff and Frederick J. Perlak

Application: Application 08/434,105, filed May 3, 1995

Title: Synthetic Plant Genes and Method for Preparation

Assignee: None (assignment to Monsanto Technology LLC recorded June 13, 2001)

Accorded benefit  
for the purpose of  
priority of: Application 07/959,506, filed October 9, 1992, now U.S. Patent 5,500,365, issued March 3, 1996; Application 07/476,661, filed February 12, 1990, now abandoned; and Application 07/315,355, filed February 24, 1989, now abandoned

SENIOR PARTY PATENT (Adang)

Named Inventors: Michael J. Adang, Thomas A. Rocheleau, Donald J. Merlo and Elizabeth E. Murray

Application: Application 08/057,191, filed May 3, 1993, now U.S. Patent 5,380,831, issued January 10, 1995

Title: Synthetic Insecticidal Crystal Protein Gene

Assignee: Mycogen Plant Science, Inc. (Paper No. 13)

Interference 103,781

Accorded benefit  
for the purpose of  
priority of: Applications 07/827,844, filed  
January 28, 1992, now abandoned,  
and Application 07/242,482, filed  
September 9, 1988, now abandoned

Count 2

Any one of Claims 1-4, 7, and 15-22 of Barton et al.'s  
Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 3, 5, and 39-43 of Fischhoff et al.'s  
Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 1-14 of Adang et al.'s  
U.S. Patent 5,380,831, which issued January 10, 1995,  
from U.S. Application 08/057,191, filed May 3, 1993.

The claims of the parties which correspond to this  
count are:

Barton et al.: Claims 1-4, 7, and 15-22

Fischhoff et al.: Claims 3, 5, and 39-43

Adang et al.: Claims 1-14.

F. Fischhoff's Preliminary Motion 8 (Paper No. 86)

By Fischhoff's uncontested Preliminary Motion 8 (Paper  
No. 86), Fischhoff moves under 37 CFR § 1.633(f) to be accorded  
benefit of the October 9, 1992, filing date of Fischhoff's U.S.  
Application 07/959,506; the February 12, 1990, filing date of  
Fischhoff's U.S. Application 07/476,661; and the February 24,  
1989, filing date of U.S. Application 07/315,355, for Fischhoff's

Interference 103,781

Proposed Counts 2, 3, and 4 (Fischhoff's Preliminary Motion 4, Paper No. 81) (Paper No. 86, p. 1). In that Fischhoff's Preliminary Motion 4 (Paper No. 81) has been denied for Proposed Counts 2, 3, and 4, this motion also is DISMISSED.

However, the declaration was redeclared in Paragraph E above with new Count 2 defining the interfering subject matter. For Count 2 of the redeclared Interference 103,781, Fischhoff has been accorded benefit for purposes of priority of the October 9, 1992, filing date of U.S. Application 07/959,506, now U.S. Patent 5,500,365, issued March 3, 1996; the February 12, 1990, filing date of U.S. Application 07/476,661, now abandoned; and the February 24, 1989, filing date of U.S. Application 07/315,355, now abandoned.

G. Fischhoff's Preliminary Motion 11 (Paper No. 89)

By Fischhoff's Preliminary 11 (Paper No. 89), Fischhoff moves under 37 CFR § 1.633(c)(2) to redefine the interfering subject matter by adding proposed Claim 46 to Fischhoff's U.S. Application 08/434,105, filed May 3, 1995 (Paper No. 90) and designating the new claim as corresponding to the count. The Motion is contingent upon granting Fischhoff's Second 37 CFR § 642 Request (Paper No. 79). Since Fischhoff's Second 37 CFR § 642 Request (Paper No. 79) has been dismissed, this motion also is DISMISSED.

Interference 103,781

H. Fischhoff's Preliminary Motion 12 (Paper No. 60)

By Fischhoff's Preliminary Motion 12 (Paper No. 60), Fischhoff moves under 37 CFR § 1.633(f) for benefit of the October 9, 1992, filing date of Fischhoff's U.S. Application 07/959,506; the February 12, 1990, filing date of Fischhoff's U.S. Application 07/476,661; and the February 25, 1989, filing date of Fischhoff's U.S. Application 07/315,355; for the subject matter defined by Adang's Proposed Substitute Count 2. Fischhoff's motion is contingent upon granting Adang's Preliminary Motion 1 (Paper No. 45). Adang's Preliminary Motion 1 (Paper No. 45) has been denied. Therefore, this motion is DISMISSED.

I. Adang's 37 CFR § 635 Motion For Order Implementing the CAFC Decision In Barton v. Adang (Paper No. 116)

In Part 3, Paragraph E, of this decision, it was ordered that this interference was redeclared, in effect implementing Barton v. Adang, 162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998) (Paper No. 118, Exh. A). Adang's unopposed Rule 635 motion is GRANTED.

J. Fischhoff's Preliminary Motion 6 (Paper No. 83)

By Fischhoff's Preliminary Motion 6 (Paper No. 83), Fischhoff moves under 37 CFR § 1.633(c)(2) to redefine the interfering subject matter by amending Fischhoff's U.S.

Interference 103,781

Application 08/434,105 to add new Claims 44 and 45 (Paper No. 84) and designating new Claims 44 and 45 as corresponding to the count, now new Count 2 (see the Order redeclaring Interference 103,781 in Part 3, paragraph E, of this decision). The motion is unopposed by Adang. Nevertheless, Fischhoff has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). To show that it is entitled to the relief sought in a motion under 37 CFR § 1.633(c)(2), the movant must (i) "[p]ropose an amended or added claim[;]" (ii) "[s]how that the claim proposed to be amended or added defines the same patentable invention as the count[;]" and (iii) "[s]how the patentability to the applicant of each claim proposed to be amended or added to the disclosure of the application . . . ." Part (b) of Fischhoff's proposed method Claim 44 and DNA coding sequence Claim 45 reads (Paper No. 83, pp. 2-3; Paper No. 84):

(b) preparing a gene encoding the same amino acid sequence as the gene selected in step (a) but which has a structural coding region with:

- (i) fewer ATTAA sequences,
- (ii) fewer plant polyadenylation signals, and
- (iii) lower A+T content[.]

Fischhoff merely presumes that the method of proposed Claim 44 and the DNA coding sequence of proposed Claim 45, both of which recite the additional step (b)(iii) of preparing a B.t. gene having a structural coding region with lower A+T content, would

have been obvious to persons having ordinary skill in the art in view of prior art including the method of modifying a wild-type structural gene which encodes an insecticidal protein of B.t. defined by Claim 3 of Fischhoff's U.S. Application 08/434,105. Claim 3 of Fischhoff's U.S. Application 08/434,105 recites the following steps:

- a) removing polyadenylation signals contained in said wild-type gene while retaining a sequence which encodes said protein; and
- b) removing ATTTA sequences contained in said wild-type gene while retaining a sequence which encodes said protein . . .[;]

Fischhoff has not satisfied its burden to show that the additional step of preparing a B.t. gene having a structural coding region with lower A+T content would have been obvious to persons having ordinary skill in the art in view of prior art teachings including Claim 3 of Fischhoff's U.S. application 08/434,105. Nor has Fischhoff shown that proposed Claims 44 and 45 including step b) would have been obvious to persons having ordinary skill in the art in view of prior art including any other claim designated as corresponding to Count 2. Thus, Fischhoff has not established that the claims proposed to be amended or added define the same patentable invention as the count.

Similarly, Fischhoff has not established that proposed Claims 44 and 45 are patentable to Fischhoff. No claim which recites step b)(iii) of proposed Claims 44 and 45 has previously been presented in Fischhoff's U.S. Application 08/434,105 for interpretation by the examiner. When considered in light of the supporting specification, step b)(iii) of preparing a gene encoding the same amino acid sequence as the gene selected in step (a) but which has a structural coding region with "lower A+T content" appears susceptible to a wide variety of interpretations. Thus, to satisfy its burden to show that proposed Claims 44 and 45 are patentable to Fischhoff, Fischhoff minimally should have shown that the meaning of the step b)(iii) would have been reasonably clear to persons having ordinary skill in the art in light of its supporting specification. Fischhoff has done no more than point to the same or substantially the same language in the specification. Accordingly, Fischhoff has not shown that it is entitled to the relief sought. Therefore, Fischhoff's Preliminary Motion 6 (Paper No. 83) under 37 CFR § 1.633(c)(2) to redefine the interfering subject matter by amending Fischhoff's U.S. Application 08/434,105 to add new Claims 44 and 45 is DENIED.

K. Fischhoff's Preliminary Motion 10 (Paper No. 88)

By Fischhoff's Preliminary Motion 10 (Paper No. 88), Fischhoff moves under 37 CFR § 1.66(c)(4) to redefine the interfering subject matter by designating (1) Claims 41-43 of Fischhoff's U.S. Application 08/434,105, and (2) Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11), as not corresponding to the count. Adang opposes the motion (Paper No. 70).

Each of Claims 41-43 of Fischhoff's U.S. Application 08/434,105 is directed to "[a] modified chimeric gene comprising a promoter which functions in plant cells operably linked to a structural coding sequence and a 3'-nontranslated region comprising a polyadenylation signal which functions in plants to cause the addition of polyadenylate nucleotides to the 3' end of the RNA" (Paper No. 88, p. 2). For the Claim 41 chimeric gene, the structural coding sequence encodes an insecticidal protein derived from B.t. tenebrionis and comprises a structurally identified 1791-nucleotide sequence (Paper No. 88, p. 2). For the Claim 42 chimeric gene, the structural coding sequence encodes an insecticidal protein derived from B.t. entomocidus and comprises a structurally identified 3567 nucleotide sequence (Paper No. 88, p. 2). For the Claim 43 chimeric gene, the structural coding sequence encodes a B.t. P2 insecticidal protein

Interference 103,781

and comprises a structurally identified 1905 nucleotide sequence (Paper No. 88, p. 2).

Each of Claims 13 and 14 of Adang's U.S. Patent 5,380,831 is directed to "[a] synthetic gene comprising [a particular segment of] the DNA sequence presented in Fig. 1" (Paper No. 88, p. 1). For Claim 13, the DNA segment spans nucleotides 1-1793 of the DNA sequence of Fig. 1. For Claim 14, the DNA segment spans nucleotides 1-1833 of the DNA sequence of Fig. 1.

Claim 40 of Fischhoff's U.S. Application 08/434,105, whose designation as corresponding to Count 2 Fischhoff does not contest, is more generally directed to (Paper No. 88, p. 1):

40. A synthetic gene which is derived from a Bacillus thuringiensis insecticidal protein toxin gene and which is more highly expressed in plants, wherein the coding sequence of said synthetic gene is modified to contain:

a) a greater number of codons preferred by the intended plant host than said insecticidal protein toxin gene; and

b) fewer polyadenylation signal sequences than said insecticidal protein toxin gene.

Adang's U.S. Patent 5,380,831 does not claim synthetic genes defined by a non-specifically identified structural coding sequence. However, Claims 1 and 4 of Adang's U.S. Patent 6,015,891 (Appendix A) read:

1. A synthetic Bacillus thuringiensis (B.t.) gene which is expressed in descendant plant cells and encodes

a pesticidal protein toxin, wherein said synthetic B.t. gene is produced by the process of:

selecting a B.t. pesticidal protein toxin desired to be expressed in a plant cell;

obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene;

using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage of the plant cell in which it is to be expressed than did the native B.t. coding sequence encoding said protein toxin, said modified coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence;

obtaining a synthetic B.t. gene comprising a coding region comprising said modified coding sequence wherein said coding region is under the control of a plant-expressible promoter;

introducing said synthetic B.t. gene into a plant cell;

culturing said cell to obtain descendant plant cells or plants comprising descendant plant cells, said descendant plant cells comprising said synthetic B.t. gene; and

establishing that said synthetic B.t. gene is expressed in said descendant plant cells.

4. A method of designing a synthetic Bacillus thuringiensis (B.t.) gene which is expressed in descendant plant cells, comprising the steps of:

selecting a B.t. pesticidal protein toxin desired to be expressed in a plant cell;

obtaining a table indicating codon usage bias for a gene or genes more highly expressed in a plant cell than a native B.t. gene;

using said table to design a modified coding sequence which encodes said protein toxin, whereby said modified coding sequence has a frequency of codon usage that more closely resembles the frequency of codon usage of the plant cell in which it is to be expressed than did the native B.t. coding sequence encoding said protein toxin, said modified coding sequence having at least about 10% of the nucleotides changed as compared to the native B.t. coding sequence;

obtaining a synthetic B.t. gene comprising a coding region comprising said modified coding sequence wherein said coding region is under the control of a plant-expressible promoter;

introducing said synthetic B.t. gene into a plant cell;

culturing said cell to obtain descendant plant cells, said descendant plant cells comprising said synthetic B.t. gene; and

establishing that said synthetic B.t. gene is expressed in said descendant plant cells.

Fischhoff argues that Claims 41-43 of Fischhoff's U.S. Application 08/434,105 and Claims 13 and 14 of Adang's U.S. Patent 5,380,831 are directed to a "separate patentable invention" from any of Fischhoff's and Adang's claims more generally directed to methods of designing synthetic genes derived from B.t. and synthetic genes derived from B.t. (Paper No. 88). Fischhoff proffers that the specific structural DNA sequences defined by Fischhoff's Claims 41-43 and Adang's 13 and 14 would not have been obvious to persons having ordinary skill in the art in view of prior art teachings including the subject matter defined by any one or all of Fischhoff's and

Adang's more general claims designated as corresponding to Count 2. To the contrary, Adang argues that the subject matter defined by one or more of Fischhoff's and Adang's general claims designated as corresponding to Count 2 would have led persons having ordinary skill in the art to make and use any one of the specific synthetic structural gene sequences designed and/or encompassed by Fischhoff's and Adang's more general claims designated as corresponding to the count with reasonable expectation that the synthetic B.t. gene produced would be more highly expressed in plants as compared to the corresponding unmodified native B.t. gene. Decision on Fischhoff's Preliminary Motion 10 is DEFERRED TO FINAL HEARING for the following reasons.

First, the evidence upon which Fischhoff and Adang may wish to rely in presenting their respective cases in chief for priority of the invention with regard to the subject matter more generally defined by Count 2 of this interference is likely to include evidence of conception and/or reduction to practice of the more limited subject matter to which Claims 41-43 of Fischhoff's U.S. Application 08/434,105 and Claims 13 and 14 of Adang's U.S. Patent 5,380,831 are directed. Any evidence Fischhoff and Adang present for or against a conclusion that Claims 41-43 of its application and Claims 13-14 of Adang's patent are directed to separate patentable inventions from

Interference 103,781

any of the more general claims of the parties designated as corresponding to Count 2 is likely to affect the weight to be accorded evidence relative to specific structural gene sequences which Fischhoff or Adang may later present for the purpose of establishing that it first conceived and/or reduced to practice an invention encompassed by the more general scope of subject matter of Count 2.

Second, if the specific structural sequences of Claims 41-43 of Fischhoff's U.S. Application 08/434,105 and Claims 13 and 14 of Adang's U.S. Patent 5,380,831 are not directed to the same patentable invention as the generic synthetic gene sequences defined by Fischhoff's and Adang's more general claims designated as corresponding to Count 2, then the adequacy of the written descriptive support for, and conception of an invention of, Fischhoff's and Adang's remaining claims designated as corresponding to Count 2, which more generally define structural gene sequences, may be questioned. See Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); and Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1-13, 62 USPQ2d 1289 (Fed. Cir. 2002), vacated-in-part, reversed-in-part,

Interference 103,781

and remanded On Petition For Rehearing Appeal 01-1230, decided July 15, 2002 (slip opinion).

Therefore, Fischhoff's Preliminary Motion 10 (Paper No. 88) is DEFERRED TO FINAL HEARING.

L. Fischhoff's Preliminary Motion 3 (Paper No. 80)

By Fischhoff's Preliminary Motion 3 (Paper No. 80), Fischhoff moves under 37 CFR § 1.633(a) for a judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11) are unpatentable under 35 U.S.C. § 112, second paragraph. According to Fischhoff, the claims of Adang's involved patent do not particularly point out and distinctly claim the subject matter Adang regards as his invention for a variety of reasons considered separately below. It is essential that this motion be considered on the merits as early in the proceedings as possible, because questions related to the patentability of claimed subject matter under 35 U.S.C. § 112, first paragraph, § 102, and § 103, for example, may not be adequately considered until the full scope of the claimed subject matter is clear.

The language for which Claims 1-10 of Adang's patent are criticized first is the phrase "a modified sequence which contains a greater number of codons preferred by the intended plant host" (Paper No. 80, pp. 6-13) which appears in independent Claim 1 (FX 11). According to Fischhoff, "there is no definition

in the '831 patent of 'codons preferred by the intended plant host" (Paper No. 80, p. 6, last full para.). However, in Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001) (Paper No. 125), the Federal Circuit stated at 1326-1327, 58 USPQ2d at 1038-1039 (emphasis added):

Mycogen contests a portion of the district court's claim construction. Specifically, Mycogen contends that the district court's definition of the "greater number of codons preferred" language in independent claims 1, 2, 13 and 14 of the '600 patent is erroneous. However, the claim construction issue here relates to both the '600 and the '862 patent, as well as the original '831 parent patent, as all three patents contain claims that use the language disputed herein. Claim 1 of the '600 patent is representative, and it reads as follows:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:
  - (a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin,
  - (b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in the codon positions II and III in a region between plant polyadenylation signals in said coding sequence;
  - (c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 31, lines 37-57 (emphasis added).

In Mycogen, district court held that:

[T]he phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

61 F.Supp.2d at 215. Thus, the district court's claim construction defines a "preferred codon" to be any codon that brings the modified Bt gene's codon frequency closer to that of the intended plant host.

The Federal Circuit said, Mycogen Plant Science Inc. v. Monsanto Co., 243 F.3d at 1327, 58 USPQ2d at 1041:

. . . Thus, the district court's claim construction regarding the "greater number of codons preferred" limitation was correct.

As indicated above, the '831 patent claim language "greater number of codons preferred," here criticized under 35 U.S.C. § 112, second paragraph, for clarity, has been construed by both the Delaware district court and the Court of Appeals for the Federal Circuit to mean that "the newly-created synthetic gene has a higher number of those codons whose frequency in the native

Interference 103,781

Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host" based on a common patent specification. Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1326-1327, 58 USPQ2d at 1038-1039. Therefore, Fischhoff's present motion under 37 CFR § 1.633(a) for judgment that Claims 1-10 of Adang's U.S. Patent 5,380,831 (FX 11) are unpatentable under 35 U.S.C. § 112, second paragraph, because the phrase "a modified sequence which contains a greater number of codons preferred by the intended plant host" (FX 11, Claim 1) does not particularly point out or distinctly claim the subject matter Adang regards as its invention must be denied. The scope of those claims of Adang's U.S. Patent 5,380,831 (FX 11) which are limited by that criticized language has been determined and is clear.

Second, Fischhoff argues that the phrases "the intended plant host" of Claim 1 and "the plant in which it is to be expressed" of Claim 11 of Adang's U.S. Patent 5,380,831 themselves render Claims 1-12 of Adang's U.S. Patent 5,380,831 vague and indefinite (Paper No. 80, pp. 14-18). The argument is based on Fischhoff's perception that skilled artisans would interpret the word "plant" in the two phrases to refer to "the whole plant," an interpretation which is inconsistent with

statements in the specification of Adang's U.S. Patent 5,380,831 (Paper No. 80, p. 14). For example, immediately following the "Frequency Of Codon Usage" listing in Adang's Table 1 (Adang's U.S. Patent 5,380,831, Table 1, col. 18), there is stated (emphasis added):

154 coding sequences of dicot nuclear genes were used to compile the codon usage table. The pooled dicot coding sequences, obtained from Genbank (release 55) or, when no Genbank file is specified, directly from the published source . . .

Thus, the step of "modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of 'the plant in which it is to be expressed'" of Claim 11 of Adang's U.S. Patent 5,380,831 would appear to read on the step of "modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which is more closely resembles the frequency of codon usage of [the nuclear genes] 'of the plant in which it is to be expressed'." According to Fischhoff, the frequency of codon usage for the whole plant is likely to differ markedly from the frequency of codon usage of the plant's nuclear genes. More particularly, Fischhoff notes from Adang's disclosure that "chloroplasts . . . have their own genome with different codon frequencies than are founds in nuclear genes" (Paper No. 80, p. 14, para. 2). See Adang's U.S.

Interference 103,781

Patent 5,380,831, col. 26, l. 27-49. In addition, Fischhoff argues that the frequency of codon usage varies considerably not only from one type of plant to another and from one type of tissue to another for the same plant, but also within each cell itself (Paper No. 80, p. 14).

Neither the Delaware district court nor the Court of Appeals for the Federal Circuit appear to have interpreted the term "plant" in the claims of Adang's patents. Presuming that the plain meaning of the term is "the whole plant," the fact that Adang's patent specification preferably modifies a portion of the coding sequence "to yield a modified sequence which contains a greater number of codons preferred by the intended plant host" (Claim 1 of Adang's U.S. Patent 5,380,831) based on the Frequency of Codon Usage Distribution Fractions compiled from 154 coding sequences of nuclear genes does not itself render the subject matter claimed vague and indefinite. Adang's specification teaches (Adang's U.S. Patent 5,380,831, col. 7, l. 11-16) (emphasis added):

[T]he frequency of preferred codon usage exhibited by a host cell can be calculated by averaging frequency of preferred codon usage in a large number of genes expressed by the host cell. It is preferable that this analysis be limited to genes that are highly expressed by the host cell.

Again, Adang's patent teaches, "[T]o optimize the efficiency of translation, codons preferred in highly expressed proteins of

the host cell are utilized" (Adang's U.S. 5,380,831, col. 9, l. 52-54). Therefore, it is not surprising that Adang's patent specification discloses, as its preferred embodiment, modification of a portion of the coding sequence "to yield a modified sequence which contains a greater number of codons preferred by the intended plant host" (Claim 1 of Adang's U.S. Patent 5,380,831) based on the Frequency of Codon Usage Distribution Fractions compiled from 154 coding sequences of nuclear genes. Claim 11 of Adang's patent specification reflects a preference for "modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed" (Claim 11 of Adang's U.S. Patent 5,380,831). Adang's patent specification teaches (Adang's U.S. 5,380,381, col. 26, l. 18-20 and 46-47):

In general, the plant codon usage pattern more closely resembles that of man and other higher eukaryotes than unicellular organisms. . . .

. . . In general, the chloroplast codon profile more closely resembles that of unicellular organisms

Adang teaches that the codon bias of its nuclear genes best reflects the codon bias of a host plant, the whole plant. Adang teaches that the codon bias of genes which are highly expressed

in the host plant best reflect the codon bias of the whole plant. While the methods of Adang's patented claims modify a coding sequence to yield a modified sequence which contains a greater number of codons preferred in the intended plant host, Adang's specification teaches that the codon preference of the whole plant is best represented by the codon preferences of nuclear genes which are highly expressed in the host plant.

Third, while Adang's patent specification does not explicitly define "analyzing the coding sequence of a gene derived from Bacillus thuringiensis which encodes an insecticidal protein toxin" (Claims 1 and 11 of Adang's U.S. 5,380,831), it is clear that the native B.t. coding sequence must be analyzed to an extent necessary for one skilled in the art to modify a portion of the native B.t. coding sequence to yield a modified sequence which either contains a greater number of codons preferred by the intended plant host than did the native B.t. coding sequence analyzed or has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed. There is nothing in the second paragraph of 35 U.S.C. § 112 which indicates that a broad step of a patentable method claim cannot be defined by its function as long as the claim language as a whole apprizes persons skilled in the art of the full scope of the method claimed. While Fischhoff prima

facie criticizes the term "analyzing" in the claimed methods as broad enough to encompass any kind of analysis which allows persons skilled in the art to modify a portion of the B.t. coding sequence as indicated, Fischhoff has not explained why the term itself does not satisfy 35 U.S.C. § 112, second paragraph, if the purpose of the analysis is clear (Paper No. 80, pp. 18-19).

There is nothing inherently wrong with broad claim language.

Fourth, Fischhoff does not argue that the U.S. District Court for the District of Delaware, U.S. District Court for the Southern District of California, or the Court of Appeals for the Federal Circuit misinterpreted the methods of Claims 1-12 of Adang's U.S. Patent 5,308,831 comprising the steps of "analyzing . . ." and "modifying . . ." as further limited by the functional phrase "of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants" (Paper No. 80, pp. 19-21). On its face, each of the methods of Claims 1 and 11 of Adang's U.S. Patent 5,380,831 comprises two steps which, upon performance thereof, are said to effectively design a synthetic Bacillus thuringiensis gene which is more highly expressed in a plant than an unmodified native B.t. gene is expressed in the same plant. Presuming the steps of the claimed methods adequately define the scope and content of the subject matter claimed, how persons skilled in the art would measure comparatively higher expression

Interference 103,781

of synthetic B.t. genes made by the methods of Claims 1-12 of Adang's patent appears to be immaterial to the patentability of the claims. Fischhoff has not shown that performance of the two steps of each of the claimed methods would not inherently design a synthetic B.t. gene which is more highly expressed in plants than the corresponding native B.t. gene.

Fifth, supported by declaratory evidence accompanied by data, Fischhoff argues that the phrase "codons preferred by the intended plant host" in Claim 1 of Adang's U.S. Patent 5,380,831 is vague and indefinite because the determinations whether codons are preferred by the intended plant host depend on the kind and number of genes used to determine the codons preferred by the plant host and the statistical differences associated with each determination (Paper No. 80, pp. 21-22). Even assuming that Fischhoff's argument has merit, Fischhoff has not shown that the scope of the claimed subject matter is vague, indefinite, and indeterminable. The Delaware district court held:

[T]he phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199, 215 (D. Del. 1999). On review, the Court of Appeals for the Federal

Circuit stated, "[T]he district court's claim construction regarding the 'greater number of codons preferred' limitation was correct." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1330, 58 USPQ2d at 1041.

Sixth, Fischhoff argues that the phrase "a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed" of Claims 11-12 of Adang's U.S. Patent 5,380,831 is itself indefinite (Paper No. 80, pp. 23-27). Initially, Fischhoff asks what the phrase "more closely resembles" means? However, the Federal Circuit indicated that the Delaware district court correctly construed the phase in context as follows:

[I]t would . . . result in a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host.

Id., 243 F.3d at 1329, 58 USPQ2d at 1041. Fischhoff has not explained why the Delaware district court's literal interpretation of the quoted claim language is unreasonable. Fischhoff acknowledges (Paper No. 80, p. 27, first full para.):

Another reasonable interpretation of claims 11 and 12 is that any one amino acid's codon distribution, if changed in the right direction, causes the sequence to have a frequency of codon usage which more closely resembles the frequency of codon usage in the host. On that basis, Dr. Barry concluded that a prior art Bt fusion gene disclosed in DeGreve et al. (which contained a greater proportion of CCC's (proline) than the native Bt gene did) fully meets the literal language of the party Adang et al.'s claims . . . .

Fischhoff has not shown that the language of Claims 1-12 of Adang's U.S. Patent No. 5,380,831 is vague, indefinite, or indeterminable. Fischhoff has not shown that persons skilled in the art reasonably would not have understood the scope of the subject matter claimed in Adang's patent. Accordingly, Fischhoff's Preliminary Motion 3 (Paper No. 80) is DENIED.

M. Fischhoff's Preliminary Motion 5 (Paper No. 82)

By Fischhoff's Preliminary Motion 5 (Paper No. 82), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 are unpatentable under 35 U.S.C. § 112, first paragraph, as based on a specification which would not have enabled one skilled in the art to make and use the full scope of the invention claimed. This motion is DEFERRED TO FINAL HEARING.

Substantial portions of Fischhoff's arguments in support of its position that the subject matter defined by Claims 1-12 of Adang's U.S. Patent 5,380,831 is broader than the enabling disclosure are devoted to the confusion persons skilled in the art would have had trying to determine the scope and content of the claimed subject matter. As Fischhoff did in its Preliminary Motion 3 (Paper No. 80), Fischhoff argues that the phrases "to be more highly expressed in plants" in Claims 1-12 of Adang's patent (Paper No. 82, pp. 5-6), "which contains a greater number

of codons preferred by the intended plant host" in Claims 1-10 of Adang's patent (Paper No. 82, pp. 6-17), and "to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed" in Claims 11-12 of Adang's patent (Paper No. 82, pp. 17-25), are inadequately defined in the patent's specification. Because the phrases purport to be vague and indefinite, Fischhoff argues that persons skilled in the art would have been required to perform undue experimentation to determine how to modify a coding sequence derived from a native B.t. gene which encodes an insecticidal protein toxin to be more highly expressed in plants. Presumably then, since Fischhoff's Preliminary Motion 3 (Paper No. 80) has been denied, this motion also should be denied. Not necessarily so.

In its revised post-trial opinion of September 8, 1999 (Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp. 2d 199 (D. Del. 1999)), the Delaware district court considered the issue whether the claims of Adang's U.S. Patents 5,567,600 and 5,567,862 are invalid for lack of enablement (Paper No. 125, Attachment H, pp. 127-135). Much of the language of Claims 1-12 and the disclosure of the specification of Adang's U.S. Patent 5,380,831 upon which Fischhoff here bases its nonenablement arguments are common to the claims and specifications of Adang's

Interference 103,781

U.S. Patents 5,567,600 and 5,567,862. The Delaware district court held that the claims of Adang's U.S. Patents 5,567,600 and 5,567,862, which include further limitations, are invalid for lack of enablement (Paper No. 125, Attachment H, pp. 127-135).

The court stated (Paper No. 125, Attachment H, pp. 134-135):

Adang and Murray have identified a specific methodology for designing a gene by modifying codon sequences to reduce certain codons and have set out in their specification an example showing how they have implemented that methodology to design a synthetic Bt gene. In claiming their invention, they have identified the methodology, but have not identified which codons or how many should be removed. In light of the number of these codons in a gene, there are millions and even billions of ways to implement their methodology as claimed, almost all of which will not achieve the desired result. The example Adang and Murray have set out [in (sic)] the specification may show an example of how they have implemented their methodology, but neither the example nor the specifications provides guidance to those skilled in the art on how the methodology should be implemented. That is, the claims and specifications do not identify which and how many codons should be removed.

Having reviewed and considered the matter, the court finds the defendants (Monsanto. Co.) have offered clear and convincing evidence which establishes that the specifications of the '600 and '862 patents are not enabling. The court will, therefore, grant the defendants motions and enter an order directing the clerk to enter judgment in favor of defendants and against plaintiff on defendants' counterclaims that the claims of the patent are invalid for lack of enablement.

Thereafter, having the issue whether the claims of Adang's U.S. Patent 5,380,831 are supported by an enabling disclosure before it on appeal from a summary judgment based on the

Interference 103,781

Delaware district court's decision that the narrower claims of the '600 and '861 patent are not enabled by their supporting specifications, the Federal Circuit remanded the issue to the U.S. District Court for the Southern District of California, stating in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 1317, 58 USPQ2d 1891, 1899 (Fed. Cir. 2001):

Monsanto's argument on appeal is that the claims are too broad to be enabled by a specification that provides only one example of an embodiment of the invention. The specification of the '831 patent, however, includes more than just one example: it contains codon usage tables, recommendations, on the preferred level of homology, and means for calculating deviation of the frequency of preferred codon usage. The proper resolution of the enablement issue is thus not sufficiently for us to direct the district court to enter summary judgment on that issue before the district court has addressed it. Accordingly, we leave it to the district court to determine whether there is a genuine issue of material fact as to enablement.

The issue here is whether Fischhoff has sustained its burden to show that the specification of Adang's U.S. Patent 5,380,831 would not have enabled persons skilled in the art to make and use the full scope of the subject matter defined by its Claims 1-12 without undue experimentation. To decide the issue, we must consider all evidence of record indicating whether or not modification of a portion of a coding sequence of a gene derived from Bt which encodes an insecticidal protein toxin to yield a modified sequence which (1) contains a greater number of codons preferred by the intended plant host than did the portion of a

Interference 103,781

coding sequence of a native gene derived from Bt which encodes an insecticidal protein toxin, and/or (2) has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed, necessarily designs a synthetic Bt gene encoding an insecticidal protein toxin which is more highly expressed in plants than a native Bt gene encoding an insecticidal protein toxin. It is anticipated that the evidence and arguments supporting the parties' cases for priority of invention will shed more light on the issue. Accordingly, Fischhoff's Preliminary Motion 5 (Paper No. 82) is DEFERRED TO FINAL HEARING.

N. Fischhoff's Preliminary Motion 9 (Paper No. 87)

By Fischhoff's Preliminary Motion 9 (Paper No. 87), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 are unpatentable under 35 U.S.C. § 112, first paragraph, for noncompliance with its written description requirement. Fischhoff's arguments in support of this motion are best represented by the following quotations:

Claim 1 of the '831 patent recites that the modified gene sequence "contains a greater number of codons preferred by the intended plant host than did said coding sequence [subjected to analysis]."  
The '482 application specification does not contain any reference to or definition of the term "greater number of codons preferred by the intended plant host."  
In the absence of any definition of this

term, the ordinary meaning of the term "greater number of codons" would include any number of codons including only one codon.

(Paper No. 87, p. 12, second full para.);

Claim 11 of the '831 patent contains mention of "frequency of codon usage" with no mention of "preferred" as a characteristic of codon usage. The '482 application specification does not contain any reference to or definition of the term "frequency of codon usage."

(Paper No. 87, p. 13, first full para.);

It was not until the amendment dated June 16, 1993 that applicants Adang et al. added claim 58, among others, which recited "a greater number of codons preferred by the intended plant host than did said coding sequence." New claim 58 was substantially identical to claim 1 of the '831 patent. The amendment cites no specification support for these new claims, but it asserts the following:

As was discussed during the May 28 interview, simply replacing unfavored codons of the native Bacillus thuringiensis (B.t.) gene with more favored codons of the intended plant host can often effect a number of the other modifications suggested by applicants in the specification.

(Paper No. 87, p. 13, last para.; footnote omitted);

Adang et al. admitted to what their invention actually was in an amendment dated June 30, 1994, during prosecution of the '191 application [(Adang's U.S. Application 08/057,191)]:

Applicants discovered that a range of sequence characteristics that are undesirable for expression in plant hosts could be minimized or eliminated by modifying the B.t. gene sequence to reflect a frequency of codon usage more closely resembling that of the intended plant host. [Emphasis added.]

Claims 1-10, in contrast, read on making just one codon substitution. Claim 12 is even broader in one respect because it reads on making just one nucleotide substitution and claim 11 is still broader because it reads on modifications without any nucleotide substitutions at all.

(Paper No. 87, p. 17; footnote omitted);

The specification must reasonably convey to one skilled in the relevant art that Adang et al. had possession of a method for enhancing expression of a Bt gene by making a single nucleotide or codon change at the time its application was filed.

Indeed in the office action dated December 11, 1990, in the '482 application, the examiner noted that claims directed to any single factor which was modified were not enabled, because modifying any single factor was unlikely to produce a useful construct. The various factors disclosed by the party Adang et al. as modifications which would produce a more highly expressed gene included the elimination of CUUGG hairpins, CG and TA doublet avoidance, the elimination of polyadenylation sequences, the elimination of polymerase II termination sequences, and the elimination of plant consensus splice sites. The party Adang et al. not only failed to provide any data supporting the operability of any such single modified sequence, but it also failed to note written description support in the specification for making only one type of modification. Clearly, Adang et al. could not point to support in the specification for a single type of modification comprising a change of only one nucleotide.

(Paper No. 87, pp. 21-22; footnote omitted); and

. . . [I]n response to the same type of undue breadth rejection, the party Adang et al. submitted a declaration by Michael G. Murray, Ph.D., which stated:

The most important consideration is to more closely approximate the frequency of codon usage of the intended plant host while avoiding sequences known to be undesirable

to plants. It is obvious that there would be a great number of possibilities for modifying a native B.t. sequence while accomplishing these goals. However, so long as these goals are accomplished, the fact that the resulting synthetic sequences differ would not cause the ordinary skilled artisan to doubt that each synthetic gene would work as taught by the Adang application.

While it is true that there would be a great number of possibilities for modifying a native B.t. gene according to the general teachings in the '831 patent, Dr. Murray's argument implies that multiple changes are needed to "accomplish those goals." In the absence of evidence that a small or specific region in the gene is particularly important to modify, one would not expect that just one or even several modifications would accomplish these goals.

(Paper No. 87, pp. 22-23; footnote omitted).

Accordingly, Fischhoff argues (Paper No. 87, p. 24):

[T]he specification of the '482 application does not reasonably convey to one skilled in the relevant art that the applicants Adang et al. had possession of a method for modifying Bt sequences comprising a single nucleotide or codon change, at the time that the '482 application was filed. Because they did not have support for the recitation of "greater number of codons" (claim 1) and "wherein the modification step comprises the substitution of at least one nucleotide," (claim 12) each of claims 1-10 and 12 is invalid under the first paragraph of 36 USC 112.

Fischhoff has not satisfied its burden to show that it is entitled to the relief sought. Fischhoff's motion is denied for the reasons stated below.

Fischhoff criticizes Adang's written description of the invention claimed in terms more pertinent to determinations that claims are unpatentable because the full scope of the subject

matter claimed therein would not have been enabled by the supporting specification. Note that Fischhoff argues that "Claim 12 is even broader . . . because it reads on making just one nucleotide substitution and claim 11 is still broader because it reads on modifications without any nucleotide substitutions at all" (Paper No. 87, p. 17); "the examiner noted that claims directed to any single factor which was modified were not enabled, because modifying any single factor was unlikely to produce a useful construct" (Paper No. 87, p. 21); "Adang et al. not only failed to provide any data supporting the operability of any such single modified sequence, but it also failed to note written description support in the specification for making only one type of modification. Clearly, Adang et al. could not point to support in the specification for a single type of modification comprising a change of only one nucleotide" (Paper No. 87, pp. 21-22); and, "In the absence of evidence that a small or specific region in the gene is particularly important to modify, one would not expect that just one or even several modifications would accomplish these goals" (Paper No. 87, p. 23).

On consideration of a movant's case for unpatentability under 35 U.S.C. § 112, first paragraph, its written description requirement and its enablement requirement should not be

Interference 103,781

confused. The court stated in Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-1564, 19 USPQ2d 1111, 1116-1117 (Fed. Cir. 1991):

This court in [In re Wilder], 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), cert. denied, 469 U.S. 1209 (1985),] (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Thus, a specification may convey that it was in possession of a broadly claimed invention and satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, without describing all species the broadly claimed invention encompasses.

Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). "[T]hat a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." In re Rasmussen, 650 F.2d 1212, 1215, 211 USPQ 323, 326 (CCPA 1981). The description requirement of the first paragraph of 35 U.S.C. § 112 is satisfied if one skilled in the art would have understood from the specification as a whole that the broader claim language defines an invention disclosed. Id. at 1216, 211 USPQ at 327, citing In re Smythe, 480 F.2d 1376,

Interference 103,781

1384, 178 USPQ 279, 285 (CCPA 1973). How close the written description must be to the language of the claimed subject matter to comply with § 112 is determined on a case-by-case basis. In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Each case must be decided on its own facts. In re Driscoll, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

In this case, Adang's patent specification teaches:

The invention disclosed herein comprises a chemically synthesized gene encoding an insecticidal protein which is functionally equivalent to a native insecticidal protein of Bt. This synthetic gene is designed to be expressed in plants at a level higher than a native Bt gene. . . . Preferably, the synthetic gene is at least approximately 85% homologous to an insecticidal protein gene of Bt.

(U.S. Patent 5,380,831, col. 3, l. 56-64);

In designing synthetic Btt genes of this invention for enhanced expression in plants, the DNA sequence of the native Btt structural gene is modified in order to contain codons preferred by highly expressed plant genes, to attain an A+T content in nucleotide base composition substantially that found in plants, and also preferably to form a plant initiation sequence, and to eliminate sequences that cause destabilization, inappropriate polyadenylation, degradation and termination of RNA and to avoid sequences that constitute secondary structure hairpins and RNA splice sites. In the synthetic genes, codons used to specify a given amino acid are selected with regard to the distribution frequency of codon usage employed in highly expressed plant genes to specify that amino acid. As is appreciated by those skilled in the art, the distribution frequency of codon usage utilized in the synthetic gene is a determinant of the level of expression. Hence, the synthetic gene is designed such that its distribution frequency of codon usage deviates,

preferably, no more than 25% from that of highly expressed plant genes and, more preferably, no more than about 10%.

(U.S. Patent 5,380,831, col. 4, l. 3-25; emphasis added);

A structural gene may contain one or more modifications in either the coding or the untranslated regions which could affect the biological activity or the chemical structure of the expression product, the rate of expression or the manner of expression control. Such modifications include, but are not limited to, mutations, insertions, deletions and substitutions of one or more nucleotides.

(U.S. Patent 5,380,831, col. 5, l. 66, to col. 6, l. 5; emphasis added);

The synthetic Bt genes of the present invention are not considered to be functionally equivalent to native Bt genes, since they are expressible at a higher level in plants than native Bt genes.

(U.S. Patent 5,380,831, col. 6, l. 64-68);

When synthesizing a gene for improved expression in a host cell it is desirable to design the gene such that its frequency of codon usage approaches the frequency of preferred codon usage of the host cell.

(U.S. Patent 5,380,831, col. 7, l. 25-28; emphasis added);

The term designed to be highly expressed as used herein refers to a level of expression of a designed gene wherein the amount of its specific mRNA transcripts produced is sufficient to be quantified in Northern blots and, thus, represents a level of specific mRNA expressed corresponding to greater than or equal to approximately 0.001% of the poly(A)+ mRNA. To date, natural Bt genes are transcribed at a level wherein the amount of specific mRNA produced is insufficient to be estimated using the Northern blot technique.

(U.S. Patent 5,380,831, col. 8, l. 8-17);

Thus, this invention is based on the recognition that expression levels of desired, recombinant insecticidal protein in transgenic plants can be improved via increased expression of stabilized mRNA transcripts; and that, conversely, detection of these stabilized RNA transcripts may be utilized to measure expression of translational product (protein).

(U.S. Patent 5,380,831, col. 8, l. 54-60); and

Experimental evidence obtained from point mutations and deletion analysis has indicated that in eukaryotic genes specific sequences are associated with post-transcriptional processing, RNA destabilization, translational termination, intron splicing and the like. These are preferably employed in the synthetic genes of this invention. In designing a bacterial gene for expression in plants, sequences which interfere with the efficacy of gene expression are eliminated.

(U.S. Patent 5,380,831, col. 10, l. 11-19; emphasis added).

While the above-quoted portions from Adang's U.S. Patent 5,380,831 indicate that point mutations in the native Bt coding sequence for insecticidal protein and/or a synthetic modification of the Bt coding sequence for insecticidal protein wherein the modification comprising the substitution and/or deletion of one nucleotide in the native Bt coding sequence may design a synthetic Bt gene to be more highly expressed in a plant, Fischhoff questions whether Adang's disclosure would have led persons skilled in the art to understand that Adang's invention comprised a method of designing a native Bt coding sequence to be more highly expressed in a plant comprising a point mutation and/or substitution or deletion of one nucleotide. A finding

that persons skilled in the art would have believed that, at the time its patented application was filed, Adang's invention comprised a method of designing native Bt coding sequence to be more highly expressed in a plant comprising a point mutation and/or substitution or deletion of one nucleotide, is supported by the following passages (Adang's U.S. Patent 5,380,831, col. 12, l. 43, to col. 12, l. 21; emphasis added):

In designing a synthetic gene for expression in plants, attempts are also made to eliminate sequences which interfere with the efficacy of gene expression. Sequences such as the plant polyadenylation signals, . . . polymerase II termination sequence, . . . UCUUCGG hairpins and plant consensus splice sites are highlighted and, if present in the native Btt coding sequence, are modified to eliminate potentially deleterious sequences.

Modifications in nucleotide sequence of the Btt coding region are also preferably made to reduce the A+T content in DNA base composition. . . . Since A+T-rich regions typify plant intergenic regions and plant regulatory regions, it is deemed prudent to reduce the A+T content. . . .

Also, a single modification (to introduce guanine in lieu of adenine) at the fourth nucleotide position in the Btt coding sequence is made in the preferred embodiment to form a sequence consonant with that believed to function as a plant initiation sequence (Taylor et al. (1987) Mol. Gen. Genet. 210: 572-577) in optimization of expression. . . .

Not all of the above-mentioned modifications of the natural Bt gene must be made in constructing a synthetic Bt gene in order to obtain enhanced expression. For example, a synthetic gene may be synthesized for other purposes in addition to that of achieving enhanced levels of expression. Under these conditions, the original sequence of the

natural Bt gene may be preserved within a region of DNA corresponding to one or more, but not all, segments used to construct the synthetic gene. Depending on the desired purpose of the gene, modification may encompass substitution of one or more, but not all, of the oligonucleotide segments used to construct the synthetic gene by a corresponding region of natural Bt sequence.

Adang's patent specifies (U.S. Patent 5,380,831, col. 15,

1. 30-55):

This invention combines the specific teachings of the present disclosure with a variety of techniques and expedients known in the art. The choice of expedients depends on variables such as the choice of insecticidal protein from a Bt strain, the extent of modification in preferred codon usage, manipulation of sequences considered to be destabilizing to RNA or sequences prematurely terminating transcription, insertions of restriction sites within the design of the synthetic gene to allow future nucleotide modifications, additions of introns or enhancer sequences to the 5' and/or 3' ends of the synthetic gene, the promoter region, the host in which a promoter region/structural gene combination is expressed, and the like. . . . The fundamental aspect of the present invention is the ability to synthesize a novel gene coding for an insecticidal protein, designed so that the protein will be expressed at an enhanced level in plants, yet so that it will retain its inherent property of insect toxicity and retain or increase its specific insecticidal activity.

Persons skilled in the art would have understood from the teaching of Adang's patent specification as a whole that the invention described therein minimally comprises a single modification of a native Bt gene encoding a insecticidal protein, e.g., the introduction, deletion or substitution at a single

Interference 103,781

nucleotide position, to enhance expression of the insecticidal protein in a plant by a detectable amount of mRNA transcripts.

The more debatable issue is, as Fischhoff suggests, whether Adang's patent specification would have enabled persons skilled in the art to make and use the full scope of the invention described and claimed. That issue is deferred to final hearing. Fischhoff has not otherwise shown that Adang's patent specification does not satisfy the written description of 35 U.S.C. § 112, first paragraph, for the subject matter claimed. Accordingly, Fischhoff's Preliminary Motion 9 (Paper No. 87) is DENIED.

O. Fischhoff's Preliminary Motion 7 (Paper No. 85)

By Fischhoff's Preliminary Motion 7 (Paper No. 85), Fischhoff moves under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 102 or § 103 (Paper No. 85, p. 1). Consideration of this motion is deferred to final hearing.

When Fischhoff filed its motion (Paper No. 85), Adang opposed the motion (Paper No. 68), and Fischhoff replied (Paper No. 107), neither party to this interference appears to have had the benefit of the interpretations of terms in its claims by the U.S. District Courts for the District of Delaware and the

Interference 103, 781

Southern District of California and the decisions of the U.S. Court of Appeals for the Federal Circuit in review thereof. It is improper to consider the patentability of claimed subject matter under the first paragraph of 35 U.S.C. § 112, 35 U.S.C. § 102, and 35 U.S.C. § 103 before the scope and content of the subject matter claimed is understood. See Panduit Corp. v. Dennison Mfg., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987) (footnote omitted):

Analysis begins with a key legal question - what is the invention claimed? Courts are required to view the claimed invention as a whole. 35 U.S.C. § 103. Claim interpretation, in light of the specification, claim language, other claims, and prosecution history, is a matter of law, and will normally control the remainder of the decisional process.

See also In re Geerdes, 491 F.2d 1260, 1262, 180 USPQ 789, 791 (CCPA 1974) ("[b]efore considering the rejections under 35 U.S.C. 103 and 112, we must first decide [what] . . . the claims include in their scope"); In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) ("the claims must be analyzed first in order to determine exactly what subject matter they encompass"); and In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962):

We do not think a rejection under 35 U.S.C. 103 should be based on . . . speculations and assumptions. We think [it] . . . wrong in relying on what at best are speculative assumptions as to the meaning of the claims and basing a rejection under 35 U.S.C. 103 thereon.

Along with filing this motion, Fischhoff moved under 37 CFR § 1.633(a) for judgment that the Adang's claims designated as corresponding to the count do not distinctly claim and particularly define the subject matter Adang regards as its invention (Fischhoff's Preliminary Motion 3 (Paper No. 80)). Therein, Fischhoff argued that the subject matter defined by Adang's claims is vague and indefinite. Considering that view, it must be assumed that the respective positions of the parties supporting and opposing this motion are based on speculation. Accordingly, it is most appropriate, informative, and efficient at this time to defer consideration of the issues presented by this motion until after the parties have had ample opportunities to comprehend the Federal Circuit's review of district courts' decisions interpreting language common to, and the scope and content of, the parties' claims designated as corresponding to the count, and reconsider and support their respective positions in that light.

Another key preliminary legal inquiry is - what is the prior art? ["Under 35 U.S.C. § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).] Before answering Graham's "content" inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102, - a legal question.

Interference 103,781

Panduit Corp. v. Dennison Mfg., 810 F.2d at 1568, 1 USPQ2d at 1597. The primary purpose of an interference proceeding is to determine priority of a commonly claimed invention, i.e., what constitutes prior art under 35 U.S.C. § 102(g). Accordingly, the issue whether Adang's claims are unpatentable under 35 U.S.C. § 103 cannot and should not be decided until the full scope and content of the prior art have been determined; the differences between the prior art and the claims at issue have been ascertained; and the level of skill in the pertinent art is resolved. Accordingly, Fischhoff' Preliminary Motion 7 (Paper No. 85) is DEFERRED TO FINAL HEARING.

P. Fischhoff's 37 CFR § 1.641(a) Request (Paper No. 110)

By Fischhoff's 37 CFR § 1.641(a) Request (Paper No. 110), Fischhoff asks the APJ "to set a time period within which each party may develop testimony and present arguments and evidence on the apparent invalidity of" Claims 1-12 of Adang's U.S. Patent 5,380,831 under 35 U.S.C. § 112, first paragraph, for noncompliance with its best mode requirement (Paper No. 110, pp. 6-7, bridging para.). As support therefor, Fischhoff argues that the APJ, exercising discretion which is permissible under 37 CFR § 1.641(a), should "conclude" that Claims 1-12 of Adang's U.S. Patent 5,380,831 are invalid for noncompliance with the best mode requirement of 35 U.S.C. § 112, first paragraph.

Interference 103,781

According to Fischhoff, it is "apparent" from the evidence that Adang's patent specification does not satisfy the best mode requirement of 35 U.S.C. § 112, first paragraph (Paper No. 110, pp. 6-7, bridging para.). Nevertheless, given that Fischhoff itself has not moved under 37 CFR 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 are unpatentable under 35 U.S.C. § 112, first paragraph, it appears that (1) the evidence to which Fischhoff points may not be sufficient to establish the invalidity of Claims 1-12 of Adang's U.S. Patent 5,380,831 under 35 U.S.C. § 112, first paragraph (best mode requirement), and (2) Fischhoff itself does not consider the evidence sufficient to establish invalidity under 35 U.S.C. § 112, first paragraph. Indeed, Fischhoff's request is confusing.

In Eli Lilly & Co. v. Barr Labs., 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001), the court said at 963, 58 USPQ2d at 1874:

Our case law explicating the best mode requirement focuses on a two-prong inquiry. . . . First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. . . . Second, if the inventor possessed a best mode the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. . . . The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. . . . The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. . . .

With respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention. . . .

In this case, it appears that the synthetic genes comprising DNA sequences of Figure 1 of Adang's U.S. Patent 5,380,831 which span nucleotides 1 through 1793 and 1 through 1833 represent specific examples of useful products which can be made by Adang's generally claimed method of designing a synthetic Bt gene to be more highly expressed in plants. However, Adang's specification makes clear that useful products made in accordance with the claimed invention are much broader in scope than the patent specification's examples, and the synthetic Bt genes comprising the DNA sequences depicted in Figure 1 and defined by Claims 13 and 14 of Adang's patent do not necessarily represent the best mode of designing a synthetic Bt gene to be more highly expressed either in plants in general or in any particular kind of plant. Adang's patent specification teaches (Adang's U.S. Patent 5,380,831, col. 15, l. 30-55):

This invention combines the specific teachings of the present disclosure with a variety of techniques and expedients known in the art. The choice of expedients depends on variables such as the choice of insecticidal protein from a Bt strain, the extent of modification in preferred codon usage, manipulation of sequences considered to be destabilizing to RNA or sequences prematurely terminating transcription, insertions of restriction sites within the design of the synthetic gene to allow future nucleotide modifications, addition of introns or enhancer sequences to the 5' and/or

3' ends of the synthetic structural gene, the promoter region, the host in which a promoter region/structural gene combination is expressed, and the like. As novel insecticidal proteins and toxic polypeptides are discovered, and as sequences responsible for enhanced cross-expression (expression of a foreign structural gene in a given host) are elucidated, those of ordinary skill will be able to select among those elements to produce "improved" synthetic genes for desired proteins having agronomic value. The fundamental aspect of the present invention is the ability to synthesize a novel gene coding for an insecticidal protein, designed so that the protein will be expressed at an enhanced level in plants, yet so that it will retain its inherent property of insect toxicity and retain or increase its specific insecticidal activity.

From the above quotation from Adang's patent, it is not at all apparent that Adang possessed a best mode generally for practicing the claimed invention at the time its patent application was filed. It is even less apparent that the invention Adang claims can have a best mode without specifying the type of plant in which the synthetic Bt gene is to be highly expressed, the particular extent and/or kind of insect infestation, the particular toxin the Bt gene is to encode, the particular amount and/or strength of the toxin the plant must produce relative to the kind of infestation and plant, etc.. Given the number of expedients influencing the design of the synthetic Bt gene to be produced by the methods generally claimed in Adang's patent, it is not apparent that Adang possessed a best mode of practicing the method generally claimed.

Moreover, in its broadest aspects, the methods claimed in Adang's patent specify that the native Bt gene is to be modified to yield a modified sequence which contains a greater number of codons preferred by the intended plant host" (Claim 1 of Adang's U. S. Patent 5,380,831) or to have a frequency of codon usage more closely resembling the frequency of codon usage of the plant in which it is to be expressed (Claim 11 of Adang's U. S. Patent 5,380,831). It is not apparent that the examples in Adang's patent do not set forth the best mode of carrying out the subject matter Adang most broadly claims to be its invention.

Since it is not apparent from the evidence to which Fischhoff points that Claims 1-12 of Adang's patent are unpatentable under 35 U.S.C. § 112, first paragraph (best mode requirement), there is no reason for the APJ to exercise discretion permissible under 37 CFR § 1.641(a) and "conclude" that Claims 1-12 of Adang's U.S. Patent 5,380,831 are invalid for noncompliance with the best mode requirement of 35 U.S.C. § 112, first paragraph, or "to set a time period within which each party may develop testimony and present arguments and evidence . . . [relative to] the apparent invalidity of" Claims 1-12 of Adang's U.S. Patent 5,380,831 under 35 U.S.C. § 112, first paragraph, for noncompliance with its best mode requirement. Fischhoff's 37 CFR § 1.641(a) Request (Paper No. 110) is DENIED.

Q. Fischhoff's Motion Under 37 CFR § 1.635  
For Temporary Stay Of Interference  
Under 37 CFR § 1.645(d) (Paper No. 118)

Fischhoff moves for a temporary stay of this interference proceeding pending the decision of the U.S. District Court for the Southern District of California in Mycogen Plant Sci., Inc., and Agrigenetics, Inc. v. Monsanto Co., Case No. 95-0653j, on Monsanto's motion for summary judgment that all claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. §§ 102(g) and 103 because of prior invention thereof by Fischhoff. In that case, Mycogen Plant Science Inc. and Agrigenetics Inc. sued Monsanto Company for infringement of its patent (Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, from U.S. Application 08/057,191, filed May 3, 1993). The U.S. District Court for the Southern District of California entered an order (Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A)) granting defendant's motion for summary judgment that Claims 1-12 of Mycogen's '831 patent are invalid under 35 U.S.C. § 102(g) and/or § 103 because Monsanto invented the subject matter thereof before Mycogen, as determined by the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp. 2d 199 (D. Del. 1999), which was affirmed in Mycogen Plant Sci., Inc. v. Monsanto Inc., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir.

Interference 103,781

2001), and denied defendant's motion for summary judgment that the contested claims of Mycogen's '831 patent are invalid for noncompliance with the enablement requirement of the first paragraph of 35 U.S.C. § 112 as moot (Paper No. 127, Exh. A).

On appeal from the decision of the U.S. District Court for the Southern District of California on motion for summary judgment in Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A), the U.S. Court of Appeals for the Federal Circuit affirmed-in-part, reversed-in-part, and remanded. Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 1309, 58 USPQ2d 1891, 1892-1893 (Fed. Cir. 2001). The Federal Circuit concluded at 1309, 58 USPQ2d at 1893, that:

. . . the district court improperly resolved disputed questions of material fact pertaining to the issue of prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding.

Id. at 1310, 58 USPQ2d at 1894, the Federal Circuit explained:

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention [claimed in the Mycogen's '831 patent] to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen

was the first to conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

Because Fischhoff moves for a temporary stay of this interference proceeding pending the decision of the U.S. District Court for the Southern District of California in Mycogen Plant Sci., Inc., and Agrigenetics, Inc. v. Monsanto Co., Case No. 95-0653j, on Monsanto's motion for summary judgment that all claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. §§ 102(g) and 103 because of prior invention thereof by Fischhoff, the decision of the U.S. District Court for the Southern District of California on Monsanto's motion for summary judgment that all claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. §§ 102(g) and 103 was entered November 10, 1999, and the district court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g)/103 was reversed on appeal to the U.S. Court of Appeals for the Federal Circuit in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 1309, 58 USPQ2d 1891, 1892-1893 (Fed. Cir. 2001), Fischhoff's motion for a temporary stay of this interference proceeding pending the decision of the U.S. District Court for the Southern District of California in Mycogen Plant

Interference 103,781

Sci., Inc., and Agrigenetics, Inc. v. Monsanto Co., Case No. 95-0653j, on Monsanto's motion for summary judgment that all claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. §§ 102(g) and 103 because of prior invention thereof by Fischhoff (Paper No. 118) is DISMISSED.

R. Fischhoff's Motion Under 37 CFR § 1.635 For Temporary Stay Of Interference Under 37 CFR § 1.645(d) Pending Outcome Of Federal Circuit Appeal Of The District Court Judgment Of Invalidity Of Claims Of The Involved Adang Patent Based On Prior Invention By Fischhoff (Paper No. 127)

The decision of the U.S. District Court for the Southern District of California on Monsanto's motion for summary judgment that all claims of Adang's U.S. Patent 5,380,831 are invalid under 35 U.S.C. §§ 102(g) and 103 was entered November 10, 1999, and the district court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g)/103 was reversed on appeal to the U.S. Court of Appeals for the Federal Circuit in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001). Thus, Fischhoff's motion for a temporary stay is moot. Fischhoff's motion (Paper No. 127) is DISMISSED.

4. Summary of Decisions on Outstanding Requests and Motions

- A. Adang Preliminary Motion 1 (Paper No. 45)  
DENIED;
- B. Adang Preliminary Motion 2 (Paper No. 46)  
DISMISSED;

- C. Adang Preliminary Motion 3 (Paper No. 47)  
DENIED;
- D. (1) Fischhoff First Rule 642 Request (Paper No. 78)  
DISMISSED;  
(1) Fischhoff Second Rule 642 Request (Paper No. 79)  
DISMISSED;
- E. Fischhoff Preliminary Motion 4 (Paper No. 81)  
DENIED;
- F. Fischhoff Preliminary Motion 8 (Paper No. 86)  
DISMISSED;
- G. Fischhoff Preliminary Motion 11 (Paper No. 89)  
DISMISSED;
- H. Fischhoff Preliminary Motion 12 (Paper No. 60)  
DISMISSED;
- I. Adang's Miscellaneous Rule 635 Motion (Paper No. 116)  
GRANTED;
- J. Fischhoff Preliminary Motion 6 (Paper No. 83)  
DENIED;
- K. Fischhoff Preliminary Motion 10 (Paper No. 88)  
DEFERRED TO FINAL HEARING;
- L. Fischhoff Preliminary Motion 3 (Paper No. 80)  
DENIED;
- M. Fischhoff Preliminary Motion 5 (Paper No. 82)  
DEFERRED TO FINAL HEARING;
- N. Fischhoff Preliminary Motion 9 (Paper No. 87)  
DENIED;
- O. Fischhoff Preliminary Motion 7 (Paper No. 85)  
DEFERRED TO FINAL HEARING;
- P. Fischhoff Rule 641 Request (Paper No. 110)  
DENIED;
- Q. Fischhoff Miscellaneous Rule 635 Motion (Paper No. 118)  
DISMISSED;
- R. Fischhoff Miscellaneous Rule 635 Motion (Paper No. 118)  
DISMISSED.

5. Order

This interference has been redeclared as Barton (U.S. Application 07/827,906) or Fischhoff (U.S. Application 08/434,105) v. Adang (U.S. Patent 5,380,831). New Count 2 defines the interfering subject matter:

Count 2

Any one of Claims 1-4, 7, and 15-22 of Barton et al.'s Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 3, 5, and 39-43 of Fischhoff et al.'s Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 1-14 of Adang et al.'s U.S. Patent 5,380,831, which issued January 10, 1995, from U.S. Application 08/057,191, filed May 3, 1993.

The claims of the parties which have been designated as corresponding to this count are:

Barton: Claims 1-4, 7, and 15-22

Fischhoff: Claims 3, 5, and 39-43

Adang: Claims 1-14.

In addition, this Decision and Order on Preliminary and Miscellaneous Motions and Requests invites the parties to consider the relationship of the subject matter defined by Count 2 of this interference to subject matter claimed in

Interference 103,781

Mycogen's U.S. Patents 6,013,523 and 6,015,891 and comment thereon.

Accordingly, it is

ORDERED that no later than thirty (30) days from the date of this Decision and Order on Preliminary and Miscellaneous Motions and Requests, the parties to this interference shall specify whether the time for filing preliminary motions should be extended;

FURTHER ORDERED that no later than thirty (30) days from the date of this Decision and Order on Preliminary and Miscellaneous Motions and Requests, the parties to this interference shall specify what additional preliminary motions, if any, and supporting evidence, if any, need be filed in this newly declared interference;

FURTHER ORDERED that no later than thirty (30) days from the date of this Decision and Order on Preliminary and Miscellaneous Motions and Requests, the parties to this interference shall explain why the additional preliminary motions and supporting evidence specified are necessary to, and should be filed in, this interference proceeding, and

FURTHER ORDERED that no later than thirty (30) days from the date of this Decision and Order on Preliminary and Miscellaneous Motions and Requests, the parties to this interference shall

Interference 103,781

recommend time periods for filing the specified additional preliminary motions, supporting evidence, oppositions, replies, motions to suppress evidence, etc.

Teddy S. Gron  
Teddy S. Gron  
Administrative Patent Judge

Interference 103,781

COUNSEL FOR JUNIOR PARTY BARTON et al.:

Lawrence M. Lavin, Jr., Esq.  
Monsanto Agricultural Company  
700 Chesterfield Parkway North - BB4F  
St. Louis, MO 63198

or

COUNSEL FOR JUNIOR PARTY FISHHOFF et al.:

Lawrence M. Lavin, Jr., Esq.  
Monsanto Company  
700 Chesterfield Parkway North, BB4F  
St. Louis, MO 63198

and

COUNSEL FOR SENIOR PARTY ADANG et al.:

Oliver R. Ashe, Jr., Esq.  
Greenblum & Bernstein, P.L.C.  
1941 Roland Clarke Place  
Reston, VA 20191

Interference 103,781

APPENDIX A